Shared decision-making in the context of Evidence-based medicine

Case study: an approach to reparative and reproductive medicine

Mariana Câncio Reis Pinto
marianacrpinto@tecnico.ulisboa.pt

Instituto Superior Técnico - Universidade de Lisboa, Lisboa, Portugal

October 2019

Abstract

The healthcare industry is trying to reinvent itself in a time where patient engagement is the challenge. Enormous amounts of information available, and conflicting advice from clinicians, media sources, acquaintances may arise, making the decision-making process difficult. Concepts like Evidence-based medicine, or Shared decision making, define approaches and frameworks on how to exercise health care. In the past few decades, contraception, abortion, sterilization and artificial reproductive technologies are the primary fields of research and in the literature of reparative and reproductive medicine. Therefore, research towards classifying the underlying causes of gynaecological conditions and infertility has been neglected. This dissertation will assess Shared decision-making in the context of Evidence-based medicine in reparative reproductive medicine. Fertility*Care* will be compared to the concept of Evidence-based medicine. Following that, the 9-item shared decision-making questionnaire will be administrated to all women and couples enrolled in the project. This will be performed to appraise the Participants perception of SDM. The average SDM-Q-9 transformed score was of $83,3$. Results were then analysed considering the consultation purpose. General follow-up to revise the charting method, Family planning consultation either to avoid or achieve a pregnancy, appointments to assess the couples' Infertility, Post-partum follow-up, and pregnancy were the five groups considered. Based on the consultation purpose of the participants, different perceptions regarding SDM lead to different overall scores on the SDM-Q-9 survey. SDM-Q-9 is subjective and presents several limitations. It cannot truly capture the absolute level of SDM but it indicates that Fertility*Care* is perceived as such by its participants.

Keywords: evidence-based medicine, shared decision-making, patient engagement, fertility awareness-based method

1. Introduction

In present society, individuals are becoming more engaged with their own healthcare. Enormous amounts of information are all around us, and there is a high offer of healthcare services and resources [2]. Given this, conflicting advice from health professionals, media sources, friends and family arise, and the decision making process becomes difficult.

How to engage patients in healthcare is a hot topic of discussion nowadays. Concepts like Evidence-based medicine and Patient-centered care or Shared decision-making appear as experimental terms to describe the best way to deliver healthcare. Large is the amount of literature published on these topics, but concrete cases of their application are scarce.

The matters of Family planning and infertility are not clearly discussed. The answers to the first go to the use of artificial contraceptives and the solution to the later is recurring to artificial reproductive technologies [11]. No foundations on women's health are at the focus of sexual education, and no attention to the causes of infertility and possible treatment solutions are targeted, just the solution.

Fertility awareness-based methods appear as important tools to both women, couples and healthcare professionals. Whether through apps, calendars, or small gadgets, these are used not only to identify fertile and infertile periods, but as an indicator for women's health. The Creighton Model Fertility*Care* system is based on the standardized observation and charting of biomarkers to assess a women's health and fertility. Its areas of intervention are infertility, spontaneous recurring miscarriage, family planning and woman's health [1].

With this work, the objective is to explore this recent reparative and reproductive medicine project in Portugal as an approach to the practice of shared decision-making.

2. Background

2.1. Evidence-based medicine

Evidence-based medicine (EBM) has been a topic of use and discussion in healthcare practice, between clinicians, public health practitioners, purchasers, planners and the population in general, for over a century. Is defined as the conscious, explicit and judicious use of the current best evidence [38] in work between a clinician and patient with the purpose of resolving, or coping with physical, mental and social problems related with the patient's health [25], considering the patient's values, preferences and expectations.

EBM has at its foundation the integration of first the best quality published evidence, second the individual clinical expertise and judgment and third the patient's values and preferences [12]. EBM aims to improve the quality of care by identifying and advancing with best practices and eliminating and discontinuing ineffective and harmful interventions.[12] The effectiveness of clinical interventions, the accuracy, and precision of diagnosis and prognosis are demands of the critical thinking promoted by EBM. Therefore, it is important for healthcare professionals to develop skills to find, critically appraise and incorporate evidence as well as to take into consideration the patient's values to make the best clinical decision.

2.2. Patient engagement in healthcare

Patient engagement in their own health care has become a reality in the last few decades. The search for healthcare services is turning into a complicated process given the enormous amount of data and resources available. Conflicting advice is a concern when an individual hears different insights from clinicians, friends and family, and even the advances in media and information technologies means [18].

Nowadays, people are at freedom whether or not to seek care and want to manage their health status. They also expect timely, reliable and effective care, where the health providers should meet their needs to give adequate information and support and demonstrate empathy and respect for their condition. However, an effective engagement implies the collaboration and support of the healthcare professional to the individual patient. Clinicians are only responsible for half of the effort to help their patients to achieve the best possible state of health [21].

Challenges arise when the medical literacy is poorly understood by the person or there is a lack in skills and motivation on the professional side. The necessity to enable greater patient embroilment in medical care can begin by making the best evidence on the most effective strategies more accessible for always busy healthcare practitioners.

Improving medical literacy

Many are the approaches to improve the individual's ability to understand medical literacy and act upon it. Formal health education and directive styles of giving advice have been overridden by newer programs and ideas.

Motivational interviewing for example, ought to encourage patients to adopt more healthy behaviours instead of just pursuing what the doctor instructs. Targeted interventions with provisioning of written and electronic information. e-learning programs and virtual support empower the individual with accessible health information material. The more personalized information the person gets, the greater impact in their engagement [20].

SDM and patient engagement

Shared decision-making, can be described as the process by which a decision that regards a patient's health should be made by information exchange and deliberation between the healthcare professional and patient, followed by a consensual decision [24].

SDM implies evidence-based information on the condition, treatment options, benefits and risks. Together with the support and guidance of the clinician and the registration and consideration of the patients preferences and concerns.

Health coaching and personalized care planning can help, for instance, individuals with long-term conditions so they can more easily manage their own health status. Self-management courses and support for chronic-condition patients is also a method to develop patient knowledge and engagement.

Decision aids: From simple fliers with information, to computer programs, Decision aids have been developed to support the decision making process. Information addressing various topics on prevention, diagnosis and treatment procedures can guide the individual in decision making. Furthermore, Decision aids can be used in structured counseling by health professionals. These methods can lead to increased patient participation, more knowledge on options' outcomes and risks, and greater confidence with decisions. However, not all available aid tools respect the standards of being evidence-based and complete, unbiased and intelligible for the person [33].

Quality of care processes

Processes can be evaluated and improved based on the feedback given by patients. Either by gathering individual responses from surveys, or by feedback meetings, there is now a wide data base for what patients identify as important and good health care. Performance data from health centers is now available to the public. This impacts the healthcare providers since it is a stimuli for continuous quality improvement [20].

Feedback from clinical care outcomes reported by patients also impacts diagnosis and condition management approaches as it raises the clinicians awareness. Physicians and health professionals often experience barriers to a more evidence-based practice. Gathering their experience with the best quality medical literature and consider the patients preference and personal case is a great challenge in an environment where time lacks [13]. Development of communication skills is a requirement for optimal patient care. The ability to clearly explain

the conditions, treatment outcomes on benefits ans risks and supporting the patient understanding. The main strategies to overcome knowledge, attitude and practice limitations are education and training.

2.3. Women's health and infertility

Every healthy women consider menstrual periods as a normal part of life. From puberty to menopause, the woman's health, mood and daily living is affected by menstrual cycles. It is thoroughly controlled by a sequence of events that involve the coordination between the hypothalamus, anterior pituitary, ovaries and endometrium. The menstrual cycle is determined by genetic influences, but is also troubled by environmental factors[28].

The reproductive life of women is expected to last an average of 36 years, having its beginning with menarche in adolescence, and ending with menopause. The 28-day cycle is considered the average case, has two main phases, the follicular and the luteal phases [35]. The period, or menstruation, is the main symptom of the existence of a cycle, and normally should occur at the end of the luteal phase and the beginning of the new follicular phase. The follicular phase has variable duration that normally can range from 10 to 23 days. This variability is what most influences the cycle length. On the other hand, the luteal phase duration ranges from 7 to 19 days, with a preponderance of 14 days length [35]. The release of an egg cell from an ovary to the Fallopian tube, ovulation, occurs after the follicular phase and before the luteal phase. In Fig. 1 a diagram of the different phases of the cycle is presented regarding the ovaries and the uterus.

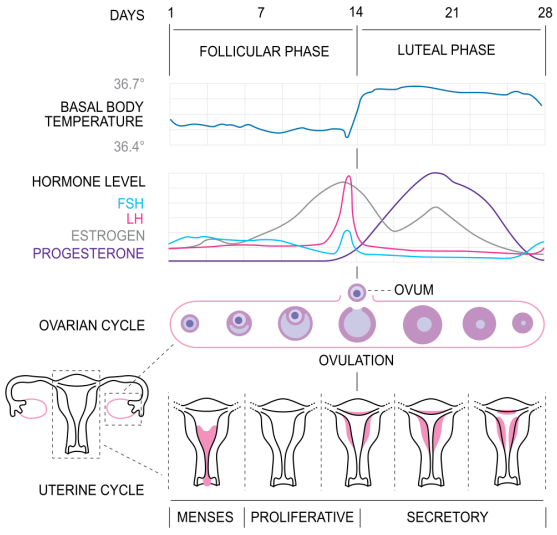

Figure 1: Diagram of the menstrual cycle [3].

The menstrual cycle is mainly regulated by hormone factors. The follicular phase of the menstrual cycle is influenced by follicle stimulating hormone, FSH, that is responsible of stimulating a few ovarian follicles, from which one will continue to maturity. As they mature, the follicle will produce and secrete estrogen that causes the lining of the uterus to grow. It also is responsible for the production of cervical mucus.

When the follicle is nearly matured, the levels of estradiol will induce the production of luteinizing hormone, LH, that will lead to ovulation. The pituitary hormones will then cause the follicle to transform into the corpus luteum, that produces progesterone, which will have a negative feedback on the secretion of FSH an LH. During the secretory phase, progesterone makes the endometrium receptive to implantation should fertilization have occurred. If fertilization does not occur, the corpus luteum will atrophy leading to a decrease in progesterone levels. Menses is then triggered and a new cycle begins.

Biomarkers of the menstrual cycle

Biomarkers are markers of a biological process or state, that can provide information useful to the clinical context. It is a characteristic that can be measured and evaluated objectively. Normal biological processes, pathogenic processes or even pharmacological responses can be studies using biomarkers [17]. The different stages of the menstrual cycle can be assessed from the observation and tracking of biological markers such as cervical secretions, the cycle length or the basal body temperature.

Cervical mucus: Cervical mucus secretions characteristics change throughout the menstrual cycle, given the estrogen and progesterone fluctuations that occur [27]. Prior to ovulation, mucus evolves from a scarce thick constitution. With the increasing levels of estradiol if the follicular phase it evolves to a more fluid and abundant state, that picks in ovulation. Following ovulation, in the luteal phase, the rising levels of progesterone cause the mucus to thicken and decrease [26].

Vaginal bleeding: Vaginal bleeding normally lasts between four and seven days, being more abundant on the first and second days. Volume can vary from 10 to 80 mL, which corresponds to about one to three tablespoons [22].

Basal body temperature: The basal body temperature (BBT) should be measured at rest. If measured at the same time, everyday, it can be used to assess a woman's fertility window. BBT is usually lower in the follicular phase of the cycle, and raises up to 0.6°C in the luteal phase, after ovulation [15].

Cycle length: Period is the first day of the menstrual cycle. The length of a cycle is highly variable, ranging from 25 to 35 days in women. This is due to the high irregularity of the follicular phase, whereas the luteal phase has a more steady average of 14 days [35].

Infertility is a disease [44]. It can be defined as the couple's inability to achieve pregnant after a reasonable period of time having sexual intercourse without the use of any contraceptive. The incapacity to achieve pregnancy through natural means, sterility, or the failure to proceed with a pregnancy until giving birth to a new born, sub-fertility, can be referred to as infertility.

The period of time up to which the couple is diagnosed as infertile varies from definition to definition. The

World Health Organization mention a minimum period of two years, but the majority of healthcare providers consider a couple as being infertile after a year actively trying to achieve pregnancy and not succeeding [16]. Given the age relation with infertility, for couples where the woman is 35 years or older, six months trying to conceive is considered a reasonable period [19].

In our present society, there is a trend to postpone childbearing within the reproductive-age population. The decision might not be fully conscious, as besides the individual reasons, there are numerous others such as social and economic factors or existing policies. This trend appears to be related with an increase in the incidence of infertility [36].

Infertility is a public health problem, and can be associated with health conditions or risk behaviours. Sexual transmitted diseases, smoking and other substances consumption, obesity or low weight among others. All this raises the necessity to develop and improve fertility awareness in the general population.

Infertility causes

Causes of infertility may dwell in a combination of female and male factors. The main female factors are ovarian dysfunction and tubal factors, that correspond to approximately 35% of all cases. Infertility caused by male factors cover 24% of the diagnostics [37]. The absence of ovulation or hormone function abnormalities are some of the causes that are at influence ovarian dysfunction. Anatomical abnormalities in the Fallopian tubes or endometriosis are among the tubal factors. Regarding male factors, ejaculatory dysfunction or infection conditions are some of the causes of infertility. Others can be undefined - idiopathic infertility - these constitute about 28% of the cases [37].

Looking for the right diagnosis

Infertility testing can be an expensive pursuit, sometimes involving invasive and uncomfortable procedures. Before starting the medical examinations and tests, the clinical history of the couple is investigated. Their sexual habits and health-related behaviours are also assessed. From that, recommendations follow to improve or create new habits that can lead to a better change of achieving a pregnancy. Infertility evaluation is performed on both men and women. Since fertility in men requires the testicles to produce sperm to be ejaculated into the vagina to meet the oocyte, and female fertility relies on the ovaries to mature and release oocytes for fertility, tests for infertility aim to find out if any of these processes are flawed [6]. Specific examinations for men include semen analysis, hormone assessment, testicular biopsy and others. For women, ovulation testing if the first test and hormone assessment follows. Contrast imaging to evaluate the anatomy and condition of the uterus and Fallopian tubes can also be done and in some cases, hysteroscopy can be performed. Despite all the efforts to find a diagnostic, at the end it may be that no specific cause was found.

Fertility awareness-based methods

Fertility awareness from a woman or couples perspective can be an important tool for health professionals. Taking the female side as example, fertility awareness can be indeed an indicator to assess women's health, besides the usefulness to identify fertile and infertile periods [42]. Fertility awareness-based methods, FABMs, help women and couples to identify the most fertile days and the infertile periods of the menstrual cycle in order to achieve or avoid pregnancy. They are defined as any method that used specific rules to assess approximately the fertile window based on the tracking of one or more of the following biomarkers: menstrual cycle duration, basal body temperature (BBT), cervical mucus, urinary hormones [41]. An overview of the most commonly used FABMs are:

Calendar methods: consider the length of the cycle, where the fertile period is calculated based on prior cycles' duration.

Mucus-only methods: based on the observations of the cervical mucus externally at vulva, the mucus consistency pattern determines the fertile window.

Basal body temperature plus considers the BBT and cycle length.

Symptothermal single check: cervical mucus and BBT assessment.

Symptothermal double-check: cervical mucus, BBT, cycle length and cervical position assessment.

Hormone monitoring through urine based on the hormones present in urine and the cycle length.

Symptohormonal: based on the hormones present in urine and the cycle length and the cervical mucus.

Treatment

The therapeutic approach to infertility is determined once its etiology is discovered. Treatment can involve only the man, or only the woman, but more commonly, the couple is involved together. Regarding male factor infertility, if the semen analysis results are abnormal, the man or couple should be referred to a fertility specialist. Ovulation occurrence evaluation determined the how to proceed when considering female factor infertility. If the phenomenon is not registered, ovulation induction should be considered. If there is a suspicion for anatomic variance or obstruction, recommendation for surgical evaluation and treatment should be made [43].

Assisted reproductive technology comprises treatments and procedures that maneuver human eggs or embryos to help a woman or couple dueling infertility become pregnant. Interventions are considered in cycles, that begin with the administration of fertility medication or ovaries' motorization for follicle development and maturation. If there is the development of oocytes, the ART procedure can be performed. Different ART interventions apply to different infertility diagnosis. Male or female gamete retrieval may be required in order to combine the oocyte and sperm to achieve fertilization. The most common procedures are [19]:

- IUI - intrauterine insemination - medical intervention that involves injecting sperm into the uterus of a woman to facilitate fertilization; IUI implies ovulation induction and sperm retrieval, but does not involve the manipulation of oocytes.

- IVF - *in vitro* fertilization - ART procedure that fertilizes an oocyte outside of the woman's body; IVF requires fertility medication for follicle development and maturation, eggs retrieval from the ovaries and sperm retrieval; the resulting embryos are transferred later through the cervix into the woman's uterus.

- ICSI - intracytoplasmatic sperm injection - laboratory procedure where a single sperm cell is injected directly into an oocyte; ICSI requires fertility medication for follicle development and maturation, eggs retrieval from the ovaries, sperm retrieval and selection; the resulting embryos are transferred later through the cervix into the woman's uterus.

The ART technique that best applies to a couple's situation is chosen based on their infertility diagnostic.

An ART cycle may accomplish a clinical pregnancy and possibly a live birth. But often they can be canceled or interrupted by a various number of reasons. Procedure difficulties like inability to obtain matured follicles, failure to complete a pregnancy until term, patient illness or decision to stop the cycle.

3. Fertility*Care*

Due to the arrival of the oral contraceptive in the 1960s, the legalization of induced abortion and the development of artificial reproductive technology procedures, the obstetrician-gynaecologists have adapted their practice. Focusing on contraception, abortion, sterilization and ARTs, the literature and research towards classifying the underlying causes of gynecological conditions and infertility has been somehow neglected.

Research on the normal and abnormal states of the woman's fertility cycle are at the basis of the creation of the Creighton Model Fertility*Care* System by the medical Dr. Thomas Hilgers and his coworkers began in 1976, in the Creighton University, USA. The System became fully described later on 1980. Furthermore, until the present investigation still continues.

It started in Omaha, Nebraska and soon expanded to Canada and Europe, to countries such as the United Kingdom, France, Netherlands, Switzerland, Poland, Ireland and others [5]. There are also Fertility*Care* centers in Africa, Asia and Oceania.

Fertility*Care* arrived to Portugal through nurse Vanessa Machado that first finished the teacher training program in 2013/15. The team is formed by Practitioners, currently three nurses, and Medical consultants, currently two medical doctors. Located in the Lisbon district, it has now expanded to Porto, Braga and Viseu, having reached more than 500 people, among women and couples.

3.1. Creighton model system

The Creighton model system, CrM system, is based on the standardized observation and charting of the biomarkers to assess a women's health and fertility. Its areas of intervention are infertility, spontaneous recurring abortion, family planning and woman's health.

Women or couples can use this method as a family planning approach to evaluate the natural fertile and infertile periods of the cycle. And, through the charting of biological markers it is possible to discover and track abnormalities in a woman's health.

CrM system relies upon a woman or couple's understanding on the presence or absence of the cervical mucus as a determinant of fertility. To this purpose, there is a standard teaching set-up and language to classify the biological markers. Natural family planning accredited practitioners follow and advise each woman or couple on the method and the ways to record their biomarkers [39].

The Creighton Model Fertility*Care* System is supported by a thorough ongoing research, accredited teaching programs for the healthcare professionals and standard teaching format throughout its centres of practice.

3.2. NaProTECHNOLOGY

Natural Procreative technology has the Creighton Model as the basis to monitor the reproductive and gynaecologic health of couples and women. Various are the applications of NaProTECHNOLOGY, that from the menstrual and fertility cycle, can target, diagnose and treat disorders and assist couples in family planning and infertility, and women's health monitoring. Hormonal assessment of the menstrual cycle, targeting disorders of ovulation, progesterone replacement therapy, pre-menstrual syndrome and post-partum depression or unusual bleeding are some of the areas of operation.

Biomarkers can be observed and recorded in a standardized, prospective and reproducible manner. The length of the cycle, pre- and post- Peak-day phases, the mucus cycle measurements, Peak day occurrence and length of menses, can be gathered and combined for a deeper understanding of the menstrual and fertility cycles, and the irregularities that can be associated with them [29].

4. Data research and methods

The objective of the present work is to assess Fertility*Care* as a Shared decision-making approach to reproductive and reparative medicine. A qualitative evaluation of whether or not Fertility*Care* respects the concept of Evidence-based medicine will be developed. Following that, the 9-item shared decision-making questionnaire, SDM-Q-9, will be administrated to all women and couples that enrolled in the project. This will be performed in order to appraise the Participants perception of SDM.

4.1. SDM-Q-9

The 9-item shared decision making questionnaire presents itself as a psychometric self-assessment tool developed to measure the practice of SDM from the patient's perspective. SDM-Q-9 is a variant from an original instrument SDM-Q - shared decision-making questionnaire - that was developed from 2001 to 2005 by a German research consortium on SDM developed an instrument to measure the exercise of SDM [32]. The survey measures the extent to which patients are involved

in the decision-making process in a clinical context. The questionnaire is available in different languages, namely Portuguese and English [10]. Portuguese was the language used for the survey. The 9-item shared decision-making questionnaire [23], SDM-Q-9 is based on the essential elements of the Makoul and Clayman's integrated model of SDM [34]. The model presents nine statements to be rated on a six-degree scale - from *completely disagree* to *completely agree*. The contents of each item are as follows:

1. Recognizing that a decision needs to be made
2. Asking for preferred involvement in decision-making
3. Informing that different options are available
4. Explaining the advantages and disadvantages of the options
5. Helping to understand the information
6. Asking for preferred option
7. Weighing the options (doctor and patient)
8. Selecting an option (doctor and patient)
9. Agreeing on how to proceed (doctor and patient)

Two questions were presented to provide more context to the participant of the questionnaire that would follow. Participants were asked to present the purpose of their last appointment with the Fertility*Care* practitioner/medical advisor. They were also asked whether any decision was made or reconsidered.

By advising the participants to consider their last follow-up appointments, they were asked to evaluate the nine statements referring to the Fertility*Care* as an approach to clinical decision-making. A score is attributed to each scale degree. Starting with zero (0) for the *completely disagree*, one (1) for the *strongly disagree* and going up to five (5) for the *completely agree* degree. The degrees given on all the nine items are transposed into rates that are summed up to obtain a raw score, that can range from 0 to the maximum of 45 points. A transformed scale, ranging from 0 to 100, can be considered, so the process can be more intuitively interpreted. This can be achieved simply by multiplying the raw score by 20/9. Zero will indicate the lowest level of SDM, whereas 100 expresses the highest level of shared decision-making.

4.2. Data treatment and analysis

General results from the participants will be displayed and described by Frequency analysis. Assessment of the number of occurrences and consider measures of central tendency, spread and variability of the data set and percentile values. For assessment of the orientation of item-by-item scores, the scores were separated into two categories. Scores from $0-2$ were grouped as "Disagree" and scores from $3-5$ were grouped as"Agree".

From the two first context questions in the questionnaire, it is possible to define groups that can be compared and analysed in order to assess perceptions of shared decision-making. First question separates participants by different appointment purposes. Such as contrast health situation, classification and women's and couples intention to engage with Fertility*Care*. Since more that two types of groups are to be compared and analysed, data is ordinal and the sample size is not grand, the Kruskal-Wallis test, H test, will be considered [7]. The H test is usually performed in order to answer the question of whether any difference exists between a set of more than 2 groups at a given significance level α. The distribution of the Kruskal-Wallis H test statistic approaches a χ^2 distribution with $k-1$ degrees of freedom, df, provided that the minimal number of observations in each group is $n_j \geq 5$. So, if the H value is greater than the Critical χ^2 value, then one can reject the null hypothesis H_0.

Second question inquires participants of whether a decision was discussed or reconsidered. Answers of Yes or No create two groups, that will answer the SDM-Q-9 with different perceptions. To compare these responses, the Mann-Whitney U test will be considered. Also, comparisons among groups with different consultation purposes can be performed. It is a non-parametric test that appears as an alternative to the Student's t-test. Because the t-test assumes normal sample distribution, the U test does not rely on distributional assumptions. The test is characterized by independent group random observations and ordinal data. If the number of scores is higher than 10, one can assume that the sampling distribution is roughly normal [8]. That is, for n_1 and n_2 large enough, the U test statistic has approximately a normal distribution $N(\mu, \sigma)$, where μ is the mean and σ represents the standard deviation. Notice that this is an approximation of a discrete distribution via a continuous one by application of a continuity correction using a z-score. From the z-score it is then possible to get the p-value, from which significance can be extracted if its value is lower comparing with the significance level α.

5. Results

The main objective of this work is to assess Fertility*Care* as a Shared decision-making practice, evidence-based reproductive and reparative medicine approach.

5.1. Evidence-based Fertility*Care*

The exercise of Evidence-based medicine is the integration of the best-appraised evidence with clinical expertise and the patient values and preferences. The Creighton Model Fertility*Care* System^{TM} is built on research developed through the last decades, an education system designed to assure the quality of service from the instructors and medical advisors, and service to the women and couples.

5.2. Fertility*Care* as a SDM approach

The questionnaire was sent to 270 women and couples that are or had been engaged with Fertility*Care*. The emails were sent in the beginning of July. A total of 61 answers were collected until the beginning of October. Considering the first part of the questionnaire, participants were asked to present the purpose of the last follow-up session. Their answers are presented in Table 1.

Five consultation purposes were registered. The majority of women and couples that took the SDM-Q-9, cor-

Table 1: Consultation purpose of the last appointment with the Fertility*Care* practitioner or medical advisor.

Consultation purpose		percentage %
Follow-up	17	28
Post-partum	7	11
Family planning	25	41
Infertility	10	16
Pregnancy	2	3
Total	61	

responding to 41% of the participants, stated that the last follow-up session was to review their Family planning approach, either to get pregnant or to avoid a pregnancy. For 16% of women and couples that attended the Fertility*Care* follow-up sessions, was to follow and investigate Infertility causes. General follow-up consultations to revise the charting method with the practitioners or medical advisors were registered by 28% of participants, and Post-partum follow-up appointments by 11% of women. Two pregnant women, 3%, attended the follow-up consultation. Regarding the question of whether a decision was discussed or revised, 77% of the participants acquiesced and the rest understood that no decision was considered in their last appointment.

Descriptive analysis of SDM-Q-9

The average SDM-Q-9 Transformed score was of $83,3$, from a range of 0 to 100.

By isolating the results by consultation purpose, differences in SDM perception become more clear. Apart from the women who were pregnant that presented the top score of 100, the highest Transformed score of 92, from a range of 69 to 100, was obtained from the group which last consultation purpose was Family planning. Following the Post-partum follow-up group, that gave an average TS of $85,1$. From the group that attended the consultation as a general Follow-up to revise the charting method, the average TS obtained was $76,1$, from a range of 27 to 100. The lowest Transformed scale was collected by the women and couples that were in the Fertility*Care* program because they were infertile.. From a range of 24 to 96, their average TS was $68,7$.

A analysis was performed by performing a Kruskal-Wallis H test on the different consultation purpose groups. Since Pregnancy follow-up group only gathered a total of two answers, the group was not considered for the test. The H test provided a strong evidence of a difference ($H = 11,65$; $p = 0,00869$ at a significance level of $\alpha = 0,05$) between the ranks of at least one pair of groups. In order to identify which pair of groups presented significant differences, Mann-Whitney U tests were performed on the six pairs of groups. The U test showed a significant difference ($U = 118,5$; $p = 0,0308$) between the Follow-up and the Family planning groups, at a significance level of $\alpha = 0,05$. Other differences were found between the Family planning and the Infertility groups ($U = 46$; $p = 0,0041$). Considering the Post-partum and the Infertility pair comparison, the approximation to the form of the normal distribution is less robust, given that the sample size of the earlier group is less than 10. Nevertheless, the test showed a difference between groups ($U = 11$; $p = 0,0220$).

On the other hand, in Table 2 the average raw and transformed scores are presented considering the answers participants gave on whether or not a decision was discussed or revised. No major differences in SDM perception were registered, and the group that stated that *No* decision was considered scored a higher average TS, of $85,9$, from a range of $24,4$ to 100, than the group that responded *Yes*. From a range of 0 to 100, the *Yes* average TS was $82,7$.

An analysis was performed to compare the the TS between the *Yes* and *No* groups of participants. A Mann-Whitney U test ($U = 221$; $p = 0,2187$; $r = 0,1587$) indicated that one cannot conclude that a significant difference exists between the group that stated *No* ($median = 97,8$) decision was discussed or revised, and the group that stated *Yes* ($median = 87,8$) to the same question.

Table 2: SDM-Q-9 average Raw score (RS) and Transformed score (TS). Item-by-item average results from all Participants (General) and considering whether a decision was discussed in the last appointment.

	General	**Yes**	**No**
I.	**4,1**	4,0	4,8
II.	**4,2**	4,1	4,7
III.	**4,0**	4,0	4,0
IV.	**4,2**	4,2	4,2
V.	**4,7**	4,6	5,0
VI.	**4,1**	4,2	4,0
VII.	**4,0**	3,9	3,9
VIII.	**3,9**	3,9	3,9
IX.	**4,3**	4,3	4,2
RS	**37,5**	37,2	38,7
TS	**83,3**	82,7	85,9

6. Discussion

Shared decision-making is a concept that is becoming more present in today's health practice. The patients role in the decision-making process is not passive, as new demands are required. Access to different sources of information, good relation between doctor and patient, care provision and risk communication are indicators of patient engagement in healthcare [20].

Decision aids have been developed to support the decision-making process. With the CrM Fertility*Care* system, women and couples are equipped with the chart and information required to correctly observe and register the biomarkers to assess a woman's health and fertility. With that material support, in every follow-up session they attend, the method is revised and any doubts or concerns are discussed with the instructor or

medical advisor.

In order to evaluate if the Fertility*Care* practice can be considered as a SDM approach, the 9-item shared decision-making questionnaire was considered [32]. The main purpose of the SDM-Q-9 questionnaire was to evaluate participants' perception of Shared decision-making. This in order to evaluate the CrM Fertility*Care* system as an approach to this practice.

Considering the different consultation purposes of the follow-up sessions and taking into account that decision-making is a process integrated by several steps, different perceptions were expected. The overall results present a high level of perception of SDM. But several differences were found when separating each step of the decision process, in the SDM-Q-9, and comparing the results between groups. The SDM-Q-9 survey has a clear unidimensional structure [23].

This can somehow obscure the complex process of shared decision-making, by giving the same importance to each one of its steps. This justifies the need to evaluate the questionnaire item-by-item. The questionnaire is theory-driven and describes SDM through key features and very practical steps seen as additive components rather than a collection of equivalent and items.

Taking in mind the appointment purposes gathered in the questionnaire, one can conclude that, regardless of the results obtained, the process of shared decision-making is distinct, depending on the reason of the follow-up session. This is a reflection of the different perspectives of the decision making process in each setting. However, all groups emphasize the step where the Fertility*Care* instructor or medical advisor helps the individual understand the information. Given that in every follow-up session one of the moments is to support any doubts or concerns the woman or couple might have, and assess their understanding on the subject.

The Infertility group revealed the lowest TS of all groups. Namely in the steps of acquiescing that a decision is to be made, and the negotiation of the different options and decision making. Given the difficult situation, the waiting for the right diagnosis and the expectancy to achieve a pregnancy, one understand the results.

No great conclusions were obtained when comparing the groups formed from the second question of the survey. It inquired the participants of whether or not a decision was discussed or reconsidered. Results showed no great difference in the transformed scores of the SDM-Q-9 among the groups, Table 2. Even the statistical test performed did not lead the conclusion that differences in perception were to be considered.

As a conclusion of the results, we can consider that Fertility*Care* can be perceived as a shared decision-making approach.

6.1. Limitations

Some limitations should be considered. The SDM-Q-9 is very practical and low-cost, it is not time consuming for the participants and is well accepted. However, self-report methods are subjective and have several limitations and so cannot truly capture the absolute level of SDM [23].

Another limitation is the representativeness of the data gathered. Only a limited number of participants responded to the questionnaire. A larger number of responses, during a larger period of time could have lead to a different set and amount of results. Data from Fertility*Care* does not yet have full digital support. This lead to some delays in sending out the online surveys, and the difficulty in gathering demographic information from the participants that took the questionnaire.

7. Conclusions

This work proposed to present Fertility*Care* as a Shared decision-making approach where patient engagement is the main focus. The concepts and basic frameworks of Evidence-based medicine and Shared decision-making are changing the grounds for the healthcare decision-making process. These new practices of healthcare should lead to better health outcomes and to a more effective use of healthcare resources [14]. And also the respect for patient autonomy and preferences. Practical problems of implementation include training on communication skills, access to research and development of tools to share evidence and support the decision process. However, many research on how to adapt guidelines and tools to facilitate these approaches are being published [31].

Fertility awareness-based methods use various biomarkers to identify days in the menstrual cycle to identify the most fertile period of the menstrual cycle. Being low cost, having no expected side effects and knowledge increase on reproductive physiology are among the advantages of using these methods [40]. The Creighton Model Fertility*Care* system is set upon the standardized observation and reporting of vaginal discharge and bleeding. The recorded biomarkers can then be interpreted for fertility and health status. Women and couples are taught using a case management approach. Fertility*Care* practitioners and medical advisors provide the instruction and follow-up sessions.

The follow-up consultations of the CrM Fertility*Care* system were the object under assessment in this dissertation. A qualitative acknowledgement of whether or not Fertility*Care* respects the three pillars of Evidence-based medicine was developed. The best available evidence is supported by decades of research and scientific evidence developed on the matter [9]. Clinical expertise is assured by the training program and internship practice prior to being certified practitioners or medical advisors [30]. Finally patient preferences and expectations are the focus of the follow-up sessions, as well as their support on doubts and concerns on the methods or procedures.

Following that, the 9-item shared decision-making questionnaire was proposed to all former and present participants of Fertility*Care*, in order to assess their perceptions of SDM concerning their last consultation with Fertility*Care*. Based on Makoul and Clayman's inte-

grated model of SDM [34], the survey inquires participants to evaluate to which level they agree with each step of the decision making process. The scores of each item were summed up to get a Raw score, raging from $0 - 45$. That score was then resized to a Transformed score, raging from $0 - 100$, for better understanding of results. The average SDM-Q-9 transformed score was of $83,3$. Results were then analysed considering the consultation purpose. General follow-up to revise the charting method, Family planning consultation either to avoid or achieve a pregnancy, appointments to assess the couples' Infertility, Post-partum follow-up, and pregnancy were the five groups considered.

Different perceptions regarding SDM, based on the consultation purpose of the participants, lead to different TS scores. The Infertility groups presented the lowest score. Those differences were analysed through a Kruskall-Wallis test, and to identify group-pair differences, Mann-Whitney tests were performed. Differences were identified between the Follow-up and Family planning groups ($U = 118,5$; $p = 0,0308$; $r = 0,3381$; $\alpha = 0,05$), between Family planning and Infertility groups ($U = 46$; $p = 0,0041$; $r = 0,4845$; $\alpha = 0,05$) and between Post-partum and Infertility groups ($U = 11$; $p = 0,0220$; $r = 0,5562$; $\alpha = 0,05$).

An inconclusive analysis was also performed considering the participants answer to the question of whether or not a decision was discussed or revised. The group that stated that *No* decision was considered scored a higher average TS, of $85,9$, from a range of $24,4 - 100$, than the group that responded *Yes*, with the average TS of $82,7$.

SDM-Q-9 as a self-report method is subjective and presents several limitations and so cannot truly capture the absolute level of Shared decision-making [23]. Another limitation was the reduced number of answers gathered from participants.

7.1. Future Work

The CrM Fertility*Care* system has great potential for improvement. The first step should be the development of better digital support platforms. One of the main difficulties of the present dissertation was the some data resources not being digitized.

There are known apps and platforms that provide a similar fertility awareness service, gathering the biomarkers information and recording them in an algorithm than can generate patters and predictions. The most noticeable example is FEMM^{TM} - Fertility Education & Medical Management. Their focus is to teach women to understand their bodies and vital signs patterns concerning their health. The support trough a free health app to help users track their health and reproductive goals. Diagnosis and treatment are supported on new research and medical protocols, and continuous research. And it offers training to individuals to become instructors of the FEMM health tracking to women and training to medical professionals in their methods and protocols [4].

A statistical appreciation of Fertility*Care* results on their areas of application, infertility, spontaneous recurring abortion, family planning and woman's health, could provide quantitative notice of their impact on women and couples that have participated in the program. For that I am more than willing to continue to collaborate.

Acknowledgements

The author would like to thank professor Mónica Oliveira, for your attention, guidance and knowledge. For always providing sharp and constructive feedback, fundamental for the work development. To nurse Vanessa and all the Fertility*Care* Portugal team, thank you for accepting my idea to study this project. It would not be possible without your help. To all professors and colleagues I met and worked with throughout these past years. Thank you Sara for being my right hand. To my parents, brothers and sisters, for their support over it all. Thank you for somehow inspiring me for the theme of this dissertation. This work could not have been done only by me, so thank you all.

References

[1] CREIGHTON MODEL FertilityCare^{TM} System.

[2] Digital Transformation in Healthcare in 2019: 7 Key Trends - Digital Authority.

[3] File:MenstrualCycle2 en.svg - Wikimedia Commons.

[4] For more information about FEMM visit www.femmhealth.org. FEMM's white paper, "The Case for FEMM," pro- vides the scientific, legal, and policy foundations for its education and healthcare model. pages 1–7.

[5] index @ fcce.naprobaby.ie.

[6] Infertility - Diagnosis and treatment - Mayo Clinic.

[7] Kruskal-Wallis Test — Real Statistics Using Excel.

[8] Mann-Whitney U Test Calculator - Calculation Details.

[9] Peer-Reviewed and Academic Literature That Supports NaProTECHNOLOGY.

[10] SDM-Q-9/SDM-Q-DOC.

[11] Suplemento sobre Fertilidade do Expresso 26-Jan-2019.pdf.

[12] A. K. Akobeng. Principles of evidence based medicine. *Archives of Disease in Childhood*, 90(8):837–840, 2005.

[13] J. M. Bae. Shared decision making: relevant concepts and facilitating strategies. *Epidemiology and health*, 39:e2017048, 2017.

[14] A. Barratt. Patient Education and Counseling Evidence Based Medicine and Shared Decision Making : The challenge of getting both evidence and preferences into health care. 73:407–412, 2008.

[15] M. L. Barron and R. J. Fehring. Is It Useful to Couples Seeking Pregnancy ? *MCN:The American Journal of Maternal/Child Nursing*, 30(5):290–296, 2005.

[16] S. Brugo-Olmedo, C. Chillik, and S. Kopelman. Definition and causes of infertility. *Reproductive BioMedicine Online*, 2(1):173–185, 2001.

[17] X.-H. Chen, S. Huang, and D. Kerr. Unit 4 • Chapter 17. Biomarkers in clinical medicine Biomarkers in clinical medicine. (2):303–322.

[18] C. M. Clancy. Patient engagement in health care. *Health Services Research*, 46(2):389–393, 2011.

[19] F. Clinic and S. Rates. 2011 A ssisted R eproductive. 2011.

[20] A. Coulter. Engaging patients in their healthcare. (April), 2006.

[21] A. Coulter. Patient engagement-what works? *Journal of Ambulatory Care Management*, 35(2):80–89, 2012.

[22] S. S. Dasharathy, S. L. Mumford, A. Z. Pollack, N. J. Perkins, D. R. Mattison, J. Wactawski-Wende, and E. F. Schisterman. Menstrual bleeding patterns among regularly menstruating women. *American Journal of Epidemiology*, 175(6):536–545, 2012.

[23] C. De las Cuevas, W. Peñate, L. Perestelo-Pérez, and P. Serrano-Aguilar. Shared decision making in psychiatric practice and the primary care setting is unique, as measured using a 9-item shared decision Making Questionnaire (SDM-Q-9). *Neuropsychiatric Disease and Treatment*, 9:1045–1052, 2013.

[24] G. Elwyn, D. Frosch, R. Thomson, N. Joseph-Williams, A. Lloyd, P. Kinnersley, E. Cording, D. Tomson, C. Dodd, S. Rollnick, A. Edwards, and M. Barry. Shared decision making: A model for clinical practice. *Journal of General Internal Medicine*, 27(10):1361–1367, 2012.

[25] G. Guyatt, R. Jaeschke, M. C. Wilson, V. M. Montori, and W. S. Richardson. Chapter 2 : What Is Evidence-Based Medicine ? pages 1–10, 2016.

[26] L. Han, E. Padua, A. Edelman, and J. T. Jensen. Appraising cervical mucus: a new approach to evaluating contraceptives. *European Journal of Contraception and Reproductive Health Care*, 23(1):78–83, 2018.

[27] L. Han, R. Taub, and J. T. Jensen. Cervical mucus and contraception: what we know and what we don't. *Contraception*, 96(5):310–321, 2017.

[28] S. M. Hawkins and M. M. Matzuk. Author Manuscript Menstrual Cycle : Basic Biology. *Annals of the New York Academy of Sciences*, 1135:10–18, 2008.

[29] T. W. Hilgers. The new women's health science of NaProTECHNOLOGY. *Archives of Perinatal Medicine*, 17(4):191–198, 2011.

[30] T. W. Hilgers. EDUCATION PHASE I: CREIGHTON MODEL FertilityCare System Allied Health Education Programs Certificate Programs for. 2020.

[31] T. C. Hoffmann, V. M. Montori, and C. Del Mar. The Connection Between Evidence-Based Medicine and Shared Decision Making Without shared decision making, EBM can turn into evidence tyranny. VIEWPOINT. *Jama*, 312(13):1295–1296, 2014.

[32] L. Kriston, A. Loh, I. Scholl, L. Hölzel, M. Härter, and D. Simon. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Education and Counseling*, 80(1):94–99, 2009.

[33] M. Lenz, S. Buhse, J. Kasper, R. Kupfer, T. Richter, and I. M??hlhauser. Decision Aids for Patients. *Deutsches Arzteblatt International*, 109(22-23):401–408, 2012.

[34] G. Makoul and M. L. Clayman. An integrative model of shared decision making in medical encounters. 60:301–312, 2006.

[35] M. Mihm, S. Gangooly, and S. Muttukrishna. The normal menstrual cycle in women. *Animal Reproduction Science*, 124(3-4):229–236, 2011.

[36] J. Pedro, T. Brandão, L. Schmidt, M. E. Costa, and M. V. Martins. What do people know about fertility? A systematic review on fertility awareness and its associated factors. *Upsala Journal of Medical Sciences*, 123(2):71–81, 2018.

[37] J. A. Rosenfeld. Infertility. *Handbook of Women's Health, Second Edition*, pages 101–108, 2009.

[38] D. L. Sackett, W. M. Rosenberg, J. Gray, R. B. Haynes, and W. S. Richardson. Evidence Based Medicine: What it is and what it isn't. *Bmj*, 312(7023):71–72, 1996.

[39] J. B. Stanford. Creighton-Model NaProEducation Technology for avoiding pregnancy. (July 1998), 2014.

[40] J. B. Stanford and C. A. Porucznik. Enrollment, Childbearing Motivations, and Intentions of Couples in the Creighton Model Effectiveness, Intentions, and Behaviors Assessment (CEIBA) Study. *Frontiers in Medicine*, 4(September):1–10, 2017.

[41] R. P. Urrutia, C. B. Polis, E. T. Jensen, M. E. Greene, E. Kennedy, and J. B. Stanford. Effectiveness of fertility awareness-based methods for pregnancy prevention: A systematic review. *Obstetrics and Gynecology*, 132(3):591–604, 2018.

[42] P. Vigil, L. F. Blackwell, M. E. Cortés, L. F. Blackwell, D. Ph, M. E. Cortés, and D. Ph. The Importance of Fertility Awareness in the Assessment of a Woman ' s Health A Review The Importance of Fertility Awareness in the Assessment of a Woman ' s Health A Review. 3639, 2013.

[43] K. R. Vitrikas, D. Grant, F. Medicine, T. Air, and F. Base. Evaluation and Treatment of Infertility. 2015.

[44] F. Zegers-hochschild, G. D. Adamson, S. Dyer, C. Racowsky, J. D. Mouzon, R. Sokol, L. Rienzi, A. Sunde, L. Schmidt, I. D. Cooke, J. L. Simpson, and S. V. D. Poel. The International Glossary on Infertility and Fertility Care , 2017 †‡ §. 32(9):1786–1801, 2017.