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Factors involved in therapeutic discordance in physician and patient relationship: a Grounded Theory study

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Introduction

For patients, therapy has a stronger meaning than prescriptions (1). Although many efficacious medical treatments exist, there is a gap between current treatment success rates and those believed to be achievable (2). Indeed, many patients, across many conditions and diseases, are not convinced that their drug is worth taking as prescribed by their physician (3 - 5). Approximately one in five new prescriptions are never filled (6), and among those filled, approximately 50% are taken incorrectly, particularly concerning timing, dosage, frequency, and duration (7). According to a World Health Organization report (2003), 50% of patients from developed countries with chronic diseases do not use their medications as recommended. These data entail a significant increase in costs for health services (8), it may cause an estimated 125,000 deaths annually (2), and at least 10 per cent of hospitalizations (9). For that, understanding the reasons why patients, do not adhere to their treatments is thus of critical importance for clinics and researchers (10, 11). Many authors have described various models of the patient-physician relationship in an attempt to reduce this gap (12), proposing recommendations about what might in order to contribute to improving the health-care outcomes and reduce the costs attributable to it (13 - 17).

Over time, the medical approach to patients is evolving. Whereas previously, patients were most often considered to be too ignorant to make decisions on their behalf, and in this context, physicians felt comfortable in making decisions on behalf of their patients (12), in the late 20th century, there has been an evolution that has led physicians to begin considering other approaches to expanded patients' involvement in making decisions about their medical care (18). This evolution can be attributed to the steady increase in people accessing medical information, overall on the internet (19, 20), who have become "active" patients (21), namely, those who as having the knowledge, skills, and confidence to manage one's health (22) and from the Evidence-Based Medicine movement (18, 23), that permitted an important mental openness by health-care professionals towards patient preferences, who view interpretation of this information as their responsibility, and others view it as an opportunity for partnership, particularly with activated patient.

The Universal Declaration of Human Rights (24) recognizes "the inherent dignity" and the "equal and inalienable rights of all members of the human family". And it is based on this concept of the person, and the fundamental dignity and equality (25) of all human beings, that the notion of patient rights was developed. In other words, what is owed to the patient as a human being, by physicians, and by the state, took shape in large part thanks to this understanding of the fundamental rights of the person (26). Health-care professionals are responsible for establishing and maintaining patients' rights (27). The idea that individual patients should have the freedom to make choices about their lives, including medical matters, has become increasingly prominent in the current literature (28). Indeed, emerge the need that physicians were adopting a more open approach, engaging both patients and their partners in a discourse of what they think about their medications (29). Since a quality health care system is co-produced by patients, families and health-care professionals working interdependently to co-create and co-deliver care (30), in this case, also the physician-patient relationship becomes an important determinant of quality health care. For the WHO (31), the relationship between physicians and patients is becoming strained, and there could be several reasons for this. Indeed, one of the most important factors is the commercialization and specialization of the practice of medicine that places a heavy reliance on technology at the cost of meaningful interaction between health-care seekers and providers at a human level. Moreover, the

WHO (31) states that the pressing demands on the physician's time and the heavy dependence on technology for diagnostic and therapeutic practices have led to a dilution of the personal touch that is so necessary for a conducive physician-patient relationship. Understanding patients' and professionals' experience during medication sharing process, could be beneficial towards improving the quality of pathways, placing the person and his needs and desires at the centre of them.

Method

This study aimed at exploring the psycho-social process that occurs when in the patient-physician relationship, treatments no longer make sense. Our research question explored "What factors contribute to the construction of therapeutic discordance between physician and patient concerning the loss of meaning of pharmacological treatment?".

Therapeutic discordance concerns a complex, sometimes ambiguous, aspect of the patient-physician relationship in the health field. The concept of therapeutic discordance lives on of the meaning given at the individual level (medical, nursing, assisted person, family member), varies from subject to subject, and depends on many elements, even if not thematized. As far as literature is concerned, it was possible to recover unexplored spaces related to the psycho-social process of therapeutic discordance in medication sharing, open above all to a qualitative investigation. The concept of therapeutic discordance is a "sensitizing concept" (32) and open and for which the need to build a consensus among all the actors involved in this complex process emerges (patients family, physicians, professionals). For this reason, in line with the goal of humanizing care and assistance processes and in such a way as to offer a reading of the phenomenon together with the emerging implications for clinical practice useful for improving this aspect of the relational process in medicine, it was considered useful and important to develop a theory based on empirical data and to holistically understand the complex process of constructing therapeutic discordance. Accordingly, we opted for Charmaz's constructivist Grounded Theory (33) (GT), in that is an interpretative research approach used in the social sciences to define psychological processes, and consists of a rigorous approach to developing theories through the iterative processes of qualitative data collection, coding, and analysis (34). The humanizing impact of this study precisely its main strength, given that it translates into practice how to put people at the centre of care in a relationship of reciprocity (35, 36).

Sampling and Material

Research setting and sampling procedures

This GT study was carried out in the province of Reggio Emilia, Italy. Specifically, the study was conducted at the Palliative Care Unit day hospital, at the Oncology Medicine ward, at the Oncology Surgery ward, at the Oncology Emergency day hospital at the Hematology ward and day hospital, at the Long-term care ward, at the Neurology ward and day hospital, at the Intensive and Sub-intensive Care Unit of the Local Health Unit - IRCCS of the Reggio Emilia Hospital "Santa Maria Nuova Hospital; moreover, this study was conducted at the Hospice "Casa Madonna dell 'Uliveto" of Montericco di Albinea, at the Medicine Department of the Montecchio Emilia Hospital "Ercole Franchini", at the 118-Emergency Operations Center of Reggio Emilia, at General Practitioner's clinic and also at the patients' home.

Although it was not possible to define all the sampling selection criteria in advance as required by the Charmaz' GT method (33), the unit of analysis of the identified research design was the patient and his network of family relationships, care, and assistance. The study was open to adult patients, as well as to health care professionals (HCPs) and other key informants, namely any individual who played a significant role in this process as perceived by patients or by the responsible figures of the different structures of the research setting (i.e., family and/or caregivers and other professional or non-professional figures).

As for patients, people who accepted a primary treatment and lived the treatment experience but decided to suspend it, both temporarily and permanently, were interviewed. When possible, dyads composed by patient and physician were interviewed, to circumscribe the phenomenon studied. In other cases, for ethical reasons, the experience of the physician and other health professionals was considered sufficient, to guarantee and protect the physician-patient relationship.

The sampling followed three steps: initial sampling, snowball sampling and theoretical sampling (33). The initial sampling was purposive, based on the research question, going to look for cases, differentiated from each other, in those contexts in which it was considered probable that the phenomenon would manifest itself in a significant way, with the support of 3 gatekeepers (37, 38). It involved 9 patients, 4 relatives and 3 HCPs. In this phase, a potential participant (patient) has decided not to take part in the study, without reporting a motivation. It was applied snowball sampling where individuals already recruited indicated further potential participants (key informants) who played a significant role for them. Subsequently, we include 4 more patients, 1 relative and 5 HCPs. During the data analysis, we applied the theoretical sampling to confirm and saturate the provisional categories. The theoretical sampling involved 3 patients and 13 additional HCPs.

Data collection and data analysis Method

Researchers started data analysis concurrently with data collection, following the GT indications for coding (33). In this phases, the lead researcher (MEDC) had regular discussions face-to-face, via telephone and e-mail with the coordinating researcher (LG), and performed all data analysis tasks with regular consultation and feedback from all the research team.

The three main tools allowed to collect useful data for the realization of the study was observation, interviews, and documents (33). Observational and interpretational memos (33) were produced for each interview and shared within the research group. In addition to observations and interviews, have been used documentary and textual data stand out, that contributed to providing useful data for the construction of the theory based on empirical data. Charmaz (33) defines the pre-existing data as those data (or texts) existing regardless of the researcher's requests and, in the specific case of the study, we consulted medical records, Advance Directives, and specialist medical advice after obtaining the participant's permission.

Two male expert interviewers, MEDC (RN, PhD Student) and LG (PhD, Qualitative Research Methodologist), who has drafted the research protocol. Data were collected and analyzed between July 2017 and March 2019. The interviews were conducted by a single researcher (MEDC or LG) in order to establish a good relationship with the participants and obtain higher quality data, while the presence of an additional observer (MEDC, LG) deemed necessary a few times. All interviewers had no professional relationship with the patients and did not work in the wards where the data were collected. The participants did not know the reason for researching in advance. When possible, the interviewer was introduced face-to-face to the patient by the gatekeeper, but mainly, the researchers contacted the participants by telephone upon acceptance agreed with the gatekeepers. Researchers also conducted group interviews (patient and family member/caregiver, HCPs), as in some cases, the participants themselves considered the experiences of those invited to join the interview to be significant. An interview was linguistically mediated by a family member (from the Albanian language to the Italian language), who also participated in the study, as he possessed a significant experience shared with the patient. A participant (HCP) was also interviewed a second time, for requests for clarification and information useful for the construction of the theory. In order to obtain greater collaboration, and considering the clinical conditions (for patients), all the interviews were conducted in places chosen by the participants. Therefore, interviews were conducted at the day hospitals of the wards, the clinics of the GPs, at the patients' bed and the participants' home.

The interviews were strategically constructed in order to allow the progress of the theory-building process to be followed and used to fill and saturate the emerged categories (33). The two interviewers had an interview guide available. The semi-structured interview addressed the following topics: the treatment; the communication; information gathering; the relationship; the emotional experience; values and priorities in everyday life. A question-stimulus was reported for each of the themes. The interviews included questions for further study and/or requests for examples taken from one's own experience. Have been defined three semi-structured interview schemes, relatively to the type of participant: patient, relatives and Healthcare Professionals (Table 1). The guide was modified as data collection proceeded to refine further questions that were not eliciting the intended information and to reflect the categories and concepts that required further development (39, 40).

Before the beginning of the interview, researchers explained to the participants the aim of the study and the need to record the interviews was explained. Also, written informed consent was obtained, and at that point, interviews began. At the end of the interview, after having thanked her, the participant was asked if there is important information that was not discussed or topics that the participant wanted to add.

Table 1 - Interview guide

Patients	Relatives	Healthcare Professionals
The treatment Could you tell me about your situation? What are you doing? What therapies do you follow? **The communication** Who sent you the proposed diagnosis/treatment? How did they tell you? What did they tell you about your situation? What did you think at that moment? And now, what do you think? Can you tell me how this communication went? Did you understand right away? Did they tell you how it will go / what physicians expect (consequences of treatment)?	**The treatment** Could you tell me from your point of view what your loved one is experiencing? How are you experiencing it? **The communication** Who was present when they communicated the proposed diagnosis/treatment? How did they communicate it? What did you think at that moment? And now, what do you think? What did you immediately understand? Have they communicated how it will go / what the physicians predict (consequences of treatment)? **Information collection**	**The treatment** Compared to Mr. / Mrs. XXXXXX., Could you tell me your clinical situation? What treatments have been proposed? How did you feel about offering that treatment? What do you think about the type of treatment proposed? **The communication** Who was present when the proposed diagnosis/treatment was communicated? How did you communicate it? What did you think at that moment? With respect to the consequences, how did the communication go?

Information collection Compared to what they told you, did you feel the need to confront someone? To retrieve other information? Where is it? From who? **The relationship** [relatives] From whom do you feel accompanied in this experience? Is there anyone you feel particularly close to? [HCPs] Compared to the healthcare staff you met, which ones did you feel closer to? With whom did you feel most comfortable? **Emotional experience** Could you tell me about what you are experiencing (the treatment proposal, treatment, etc.), what emotions do you feel? How do you feel about handling this? **Values and priorities in everyday life** Compared to the treatment, what did you think? How have they been proposed to you in relation to your life, your week? What do you think about the consequences of your treatment? How do you plan to manage them? What do you expect for the future?	Compared to what was said to your loved one, as a caregiver did you feel the need to confront someone? To retrieve other information? Where is it? From who? **The relationship** [relatives] From whom do you feel accompanied in this experience? Have you confided in someone you feel particularly close to? [HCPs] Compared to the healthcare staff you met, which ones did you feel closer to? With whom did you feel most comfortable? **Emotional experience** Could you tell me about what you are experiencing (the treatment proposal, treatment, etc.), what emotions do you feel? How do you feel about handling this? **Values and priorities in everyday life** Compared to the treatment, what did you think? What do you think about the consequences of the treatment? How do you plan to manage them? What do you expect for the future?	**Information collection** What information did you give to Mr / Mrs. XXXXXX? Did the client ask for something in particular? Usually, what do they ask you in this kind of situation? **The relationship** How do you live the relationship with the patient to whom you proposed this treatment? Could you tell me an episode that you think is significant? And what happens between you and your family, if present? Could you tell me an episode that you think is significant? **Emotional experience** Could you tell me about the treatment, treatment proposal, how do you feel? What emotions do you feel? How do you feel about handling this? **Values and priorities in everyday life** Compared to the treatment, what do you think? When is it offered? What do you think about the consequences of the treatment?

Subsequently, to those who took part in the initial sampling, was asked to suggest other people, encountered during the process for which was interviewed, to be able to interview too (snowball sampling). At the end of the interview, at all the participants were asked to answer the questions useful for collecting socio-demographic data such as age, sex, marital status, place of residence, level of studies, work situation, presence of family members at home, in order to fill out a participant form. Additionally, the interviewers asked the participants about the opportunity to meet a second time in the case of doubts in the interpretation of the collected data.

The interviews lasted between 10 and 105 min, with an average of 38 min. Interviews were recorded and professionally transcribed within 48 hr from their completion. The participants were allowed to read the transcript if requested. None patient asked to read the interview to confirm the content.

Researchers followed the following analytical steps: 1. ***Open coding:*** in which researchers who conducted the interviews indexed them building codes, staying at a level close to the data, analyzing them word-by-word and line-by-line, opening them in all possible directions of sense, and shared the data with the research team; 2. ***Focused coding:*** through which the researchers have raised the level of conceptualization, starting from the descriptive path to the conceptualization phase, collecting the concepts into categories and identify concepts at a higher level of abstraction. At this level, the connection between the categories started, together with their properties. The abductive process put in place allowed the researchers to corroborate and saturate the provisional categories. By use of analytical memos, were defined as the type of participant characteristics needed to diversify our sample further and saturate (collect information until interviews no longer yielded new elements of insights) the categories. In consideration of the new data from collected by each new participant, researchers were able to simplify and reduce many of the initially emerging categories and to identify the need to explore further settings, to help the researchers best form the theory; 3. ***Theoretical coding:*** in which researchers highlighted the relationships between the conceptual categories and defined the core category and until reach the understanding of the theoretical model. Researchers stopped data collection when the analysis reached both data and meaning saturation of the categories, confirming the endpoint of the emerging theory.

The theoretical coding has concerned data coming from patients and physicians since outside of this dyad, and no significant data emerged useful for constructing the theoretical model. Indeed, although also relatives and other non-medical health professionals have been involved, in this study emerge that these type of participants do not influence the decision-making process. This allowed us to identify and understand the boundaries of our theoretical model.

Trustworthiness/Rigor

In some cases, triangulation of interview data from multiple sources (patients, relatives, and health care professionals) on a single event served to increase the internal validity of this study (41). Analyzing multiple cases was strengthens external validity. In order to enhance the trustworthiness of findings, researchers used team consensus-building discussions at all three phases of coding. The research team also maintained a detailed audit trail of all coding and data-related decision making. An external audit (37) was completed at project completion, confirming that the research process was thorough and the quality and nature of the findings were congruent with the process.

Ethical Considerations

The Provincial Ethics Committee of Reggio Emilia approved the study (Protocol n. prot. n. 30152 of 2016/12/21) with provision 2017/DIRSC/0012 of 2017/06/20. The research was conducted following the International Council for Harmonisation (ICH) E6 – good clinical practice (GCP) (R2) Guidelines (42) and the principles of the Declaration of Helsinki (43). The study and its report followed the consolidated criteria for explicit and comprehensive reporting of qualitative research checklist (44) (Appendix s1).

Results

The final sample (Table 2) of our study was composed of 16 patients, 21 health professionals (including 14 physicians and 5 non-physicians) and 5 relatives, for a total of 42 respondents. 35 interviews were conducted, including 7 group interviews, while a participant was interviewed at a later time, far from the first interview, to obtain useful data for the reflection of the emerging categories. The average age of our respondents is 53, with a range ranging from 25 to 83 years. 25 respondents belonged to the female gender, while 17 belonged to the male gender. As for the professions, among the participants interviewed as patients and family members, 1 was an architect, 3 were housewives, 1 was a cook, 8 were employed, 1 was an agricultural entrepreneur, 1 was an entrepreneur, 3 were nurses, 1 was a worker, 1 was a freelancer and 1 was social health operator. As for health professionals, 2 were haematology physicians (one of whom was in charge of the OU), 2 were palliativist physicians, 1 was a physician in charge of the OU (internist), 1 was a physiotherapist, 2 were medical oncologists, 1 was a neurologist, 2 they were GPs, 2 were anesthesiologists, 1 was a nursing coordinator, 6 were nurses, 1 was a physiotherapist. The patients (n = 16) were interviewed about the experiences of the treatments for the following respective pathological states: Hodgkin's Lymphoma - Nivolumab (n = 1), Leukemia - Lenalidomide (n = 1), Hepatocellular Carcinoma - Chemotherapy/Radiotherapy (n = 2), Advanced Metastatic Breast Carcinoma - Ribociclib (n = 1), Amyotrophic Lateral Sclerosis - Riluzole Zentiva (n = 2), Graft Versus Host Disease - Methotrexate (n = 1), Type 1 Diabetes Mellitus - Insulin (n = 1), Seasonal Influenza - Influenza Vaccine (n = 3), Heart Failure - K-drip/Furosemide (n = 1), Myasthenia Gravis - Pyridostigmine Bromide (n = 1); Spinal Cord Injury – Paracetamol/Codeine (n = 1), Epilepsy - Phenobarbital (n = 1).

Table 2 - Sampling, setting and participant's characteristics

Participant	Code	Age	Gender	Profession	Sampling	Setting	Patient's pathological states	Treatment
Patient	P-01	65	M	Employee	Initial	Palliative Care Unit day hospital	Hodgkin's Lymphoma	Nivolumab
HCP	HCP-01	39	F	Haematologist	Initial	Hematology ward		
Relative	RL-01	63	F	Employee	Snowball	Palliative Care Unit day hospital		
HCP	HCP-02	57	M	Medical Director - Haematologist	Snowball	Hematology ward		
Patient	P-02	78	M	Employee	Snowball	Home	Leukemia	Lenalidomide
Patient	P-03	83	F	Employee	Initial	Hospice	Hepatocellular Carcinoma	Chemotherapy / Radiotherapy
Patient	P-04	45	F	Employee	Initial	Hospice	Metastatic Breast Carcinoma	Ribociclib
HCP	HCP-03	62	M	Palliativist physician	Snowball	Hospice		
Relative	RL-02	47	F	Employee	Initial	Home		
Patient	P-05	75	F	Housewife	Initial	Home	Amyotrophic Lateral Sclerosis	Riluzole Zentiva
Patient	P-06	73	M	Architect	Initial	Home	Hepatocellular Carcinoma	Chemotherapy / Radiotherapy
HCP	HCP-04	53	F	Physiotherapist	Initial	Oncology Medicine ward		
Relative	RL-03	68	F	Housewife	Initial	Home		
Patient	P-07	72	M	Employee	Initial	Home	Amyotrophic Lateral Sclerosis	Riluzole Zentiva
Relative	RL-04	47	M	Freelancer	Initial	Oncology Medicine ward		
Patient	P-08	46	F	Employee	Initial	Oncology Medicine ward	Graft Versus Host Disease	Methotrexate
Relative	RL-05	42	M	Business owner	Initial	Medicine Ward		
Patient	P-09	76	F	Housewife	Initial	Medicine Ward	Type I Diabetes Mellitus	Insulin
Patient	P-10	62	F	Nurse	Initial	Medicine Ward	Seasonal Influenza	Seasonal influenza vaccination
Patient	P-11	52	F	Nurse	Snowball	Medicine Ward	Seasonal Influenza	Seasonal influenza vaccination
Patient	P-12	48	F	Nurse	Snowball	Medicine Ward	Seasonal Influenza	Seasonal influenza vaccination
HCP	HCP-05	42	F	Nurse	Initial	Long-term care ward		
Patient	P-13	57	M	Cook	Snowball	Medicine Ward	Heart Failure	K-drip / furosemide

HCP	HCP-06	39	F	Palliativist physician	Snowball	Palliative Care Unit day hospital		
HCP	HCP-07	32	F	Nurse	Snowball	Palliative Care Unit day hospital		
HCP	HCP-08	44	F	Nurse	Snowball	Palliative Care Unit day hospital		
HCP	HCP-09	56	M	Neurologist	Theoretical	Neurology day hospital		
HCP	HCP-10	58	M	Medical Director - Internist	Theoretical	Medicine Ward		
Patient	P-14	25	F	Healthcare Assistant	Theoretical	Neurology ward	Myasthenia Gravis	Pyridostigmine Bromide
Patient	P-15	43	M	Farmer	Theoretical	Home	Spinal Cord Injury	Paracetamol/Codeine
HCP	HCP-11	37	F	Nurse	Theoretical	Medicine Ward		
Patient	P-16	50	M	Worker	Theoretical	Long-term care ward	Epilepsy	Phenobarbital
HCP	HCP-12	55	M	General practitioner	Theoretical	General Practitioner clinic		
HCP	HCP-13	39	F	Nurse	Theoretical	118-Emergency Operations Center		
HCP	HCP-14	55	F	Anesthetist	Theoretical	Intensive Care Unit		
HCP	HCP-15	44	F	Anesthetist	Theoretical	Intensive Care Unit		
HCP	HCP-16	41	F	Nursing coordinator	Theoretical	Sub-intensive Care Unit		
HCP	HCP-17	44	F	Nurse	Theoretical	Sub-intensive Care Unit		
HCP	HCP-18	55	M	Oncologist	Theoretical	Oncology Medicine ward		
HCP	HCP-19	34	F	Oncologist	Theoretical	Oncology Emergency day hospital		
HCP	HCP-20	67	M	General practitioner	Theoretical	General Practitioner clinic		
HCP	HCP-21	59	M	Medical Director - Oncological surgeon	Theoretical	Oncology Surgery ward		

Findings

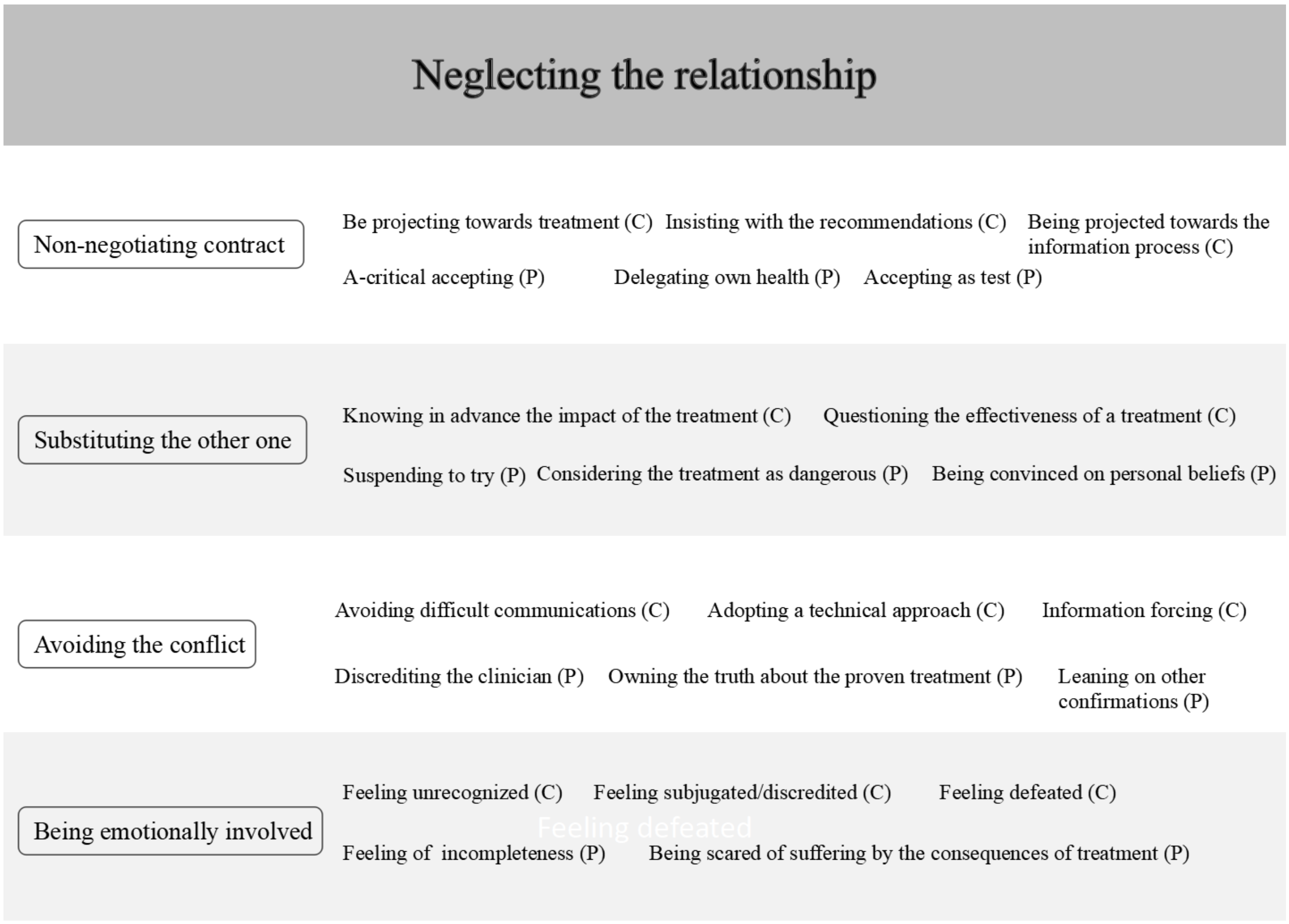
When in the physician-patient relationship, both explicitly and implicitly, the possibility of pharmacological treatment is presented, discordant interactions can come into play, bringing the relationship on a path that does not respond to the reason why this relationship was activated. "Therapeutic discordance" theory resulting from the data analysis of our study is expressed as a set of factors, not always cohesively correlated with each other, and can adequately account for all the data collected from the interviews to the sample.

Core category

Neglecting the relationships

What happens in therapeutic discordance theoretical model is a process in which several factors are involved that make both patients and health professionals mutually unwanted from the commitment that involves involvement in starting and maintaining a constructive therapeutic relationship. The core category emerged in this study is called "neglecting the relationship", and allows to understand and focus the categories in a conceptual framework, explaining the factors that are involved in the complex process of a discordant therapeutic relationship. The central concept is that the therapeutic partnership goes through a delicate and complex negotiation process, which is disregarded by the participants in the process itself, at different times, and with different nuances, or even may not be present, opening a relational gap between the participants in the process; a process that does not cease to exist, but takes a different turn from the one imagined when it started. Neglecting the relationship holds together 4 categories: *non-negotiated contract; replace the other; avoiding the conflict* and *emotional factors* (see Figure 1 and Table 3).

Figure 1 – Therapeutic discordance theoretical model



Abbreviations: C, clinicians; P, patients

Table 3 - Conceptual explanation of main categories emerged

Main categories	Conceptual explanation
Non-negotiating contract	When, during the physician patient-interaction, the possibility of starting a treatment emerges, factors can being activated that in the future could compromise the success of the therapeutic relationship, through a non-negotiated contract. While the physician, projected towards a treatment proposal, supported by his role and his science, activates a path of information towards the patient, not considering the feedback; at the same, the patient time is projected towards an unconditional acceptance, placing his trust in the role of the physician, accepting the proposal to try, reserving the space for later to evaluate efficacy and effects on his own skin.

Substituting the other one	In some cases, during the therapeutic relationship, factors may emerge that lead the process participants to take the place of one another. The physician, once he has obtained the information concerning the patient's condition, believing that he is aware of the real impact that he could have on the patient's health, or of the real efficacy of the treatment, may decide not to propose a treatment. The patient, on the other hand, can neglect the relationship with the caregiver, stealthily deciding to suspend to try what happens, considering the treatment dangerous, or by leveraging his convictions, matured in his cultural context.
Avoiding the conflict	After the patient has undertaken the therapeutic path and having tried it on his own body, factors can emerge that lead the participants to circumvent the conflict, effectively removing the relationship and the sharing of the decisions taken. The physician is inclined to adopt strategies to avoid difficult communications, through the adoption of a more technical and less relational approach, and in case of communication of the patient is suspended, the physician is led to adopt a paternalistic approach, leaving alone the patient in the decision-making process. The patient, strong in the experience of the treatment, considers himself able to assess the physician's skills, discrediting him, and sometimes, relying on confirmations received from outside the relationship.
Being emotionally involved	In the theoretical model emerges the involvement of emotional factors which are also involved in the removal of the constructive relationship between physician and patient. The physician, faced with a suspension of treatment decided by the patient, can see that his role is lost, feeling subjugated, defeated, losing control of his part regarding the therapeutic relationship. The patient, instead, not finding an adequate answer to his problem, reports a sense of incompleteness, while in the case in which the evaluations are carried out based on the experiences of others, he may feel afraid because of the consequences attributed to the treatment.

Main conceptual categories

Non-negotiating contract

This conceptual category concerns the moment of the proposal and the acceptance of the treatment and offers an explanation of the way in which the relationship is polarized both by the physician and by the patient. It is important to emphasize this aspect, from the moment in which, in this initial period, decisive factors are activated for the success or failure of the intentional relationship process in the therapeutic partnership. From our data, it emerged that, during the treatment proposal, the physician omits the patient's feedback, while the patient accepts, even if he does not have a complete picture of the drug and what it means to take it. Thus giving birth to a non-negotiated contract.

Being projected towards treatment

From our data it appears that the physician is projected towards a treatment to be proposed, feeling obliged to offer treatment, from the moment it is activated an intentional interaction, with an explicit request that comes from the patient, namely to restore his health conditions.

Yes, yes. And then they tell me "what if it doesn't work?" I reply "and if it doesn't work, we will think about it when the time comes because, now ..." but also to say, too many things at once, then later ... the information is not retained or is not retained in the right way so ... mmm ... when instead we notice or that the therapy has worked for a period, or it just doesn't work, and after that the meeting, clearly it is a little more challenging (HCP-01)

No, no, certainly there were no certainties. From the moment this relationship was clear, that is, he knew that it could work but also not, and that it would have functioned at term, because, it's not like I was sure at the time. Perhaps sooner or later the drug will lose the answer (HCP-21);

Insisting with the recommendations

The physician tends to adopt a paternalistic approach, in order to adequately respond to his own role, to the situation he faces, this leads him to insist on the importance of his recommendations. This approach, for the professional, is also supported by scientific evidence regarding treatments, evidence that often have a safety significance for the physician, as they enable the practitioner to possess the knowledge necessary to satisfy the patient's request.

... and therefore every time I have to explain to the person that the therapy is the one, that he must listen to me, it is not that there are alternatives and then is needed make him understand. You can't improvise, you can't mess with health (HCP-09)

... for its pathology, advanced heart failure, in its clinical conditions, Furosemide and potassium are fundamental therapies even according to the evidence, so, I don't consider them futile, and that's why I make them do it ... (HCP-10)

Being projected towards the information process

In any case, the physician, aware of the fact that his recommendations may be disregarded, reserves the right not to obtain the desired effect in the relational process, merely contenting himself with the information provided to the patient.

... when I visit him, returned from the hospital, prescribe therapy as decided by the hospital physician. And it is a useless effort because I know that he will not take it, I know that he will continue to do what he has always done ... I know he will decompensate and return to the hospital to seek treatment ... (HCP-12).

A-critical accepting

As for patients, the data showed that acceptance of physician's recommendations does not go through a negotiation process. In fact, the acceptance by the patient turns out to be uncritical, not having experienced the treatment experience.

but it is not that it has made me effect ... to say, whatever I was proposed by Dr. XXXX, hence, I gave the maximum confidence and it went well. Indeed, as a spirit, I always told myself that you have to find the pers ... trust a person and that's it. Otherwise, you go around the world, go to that center there, here is this here, the holy man, after you go around the world and ... (P-01)

Delegating own health

The patient attributes greater weight to the physician's skills than his / her ability to assess the offer, delegating his / her health, placing the utmost confidence in the role of the physician.

.. because I repeat full delegation .. also because I said .. I often say to Dr. XXXX "You are a physician, I am an engineer, if you want a wonderful house I do it to you.. but repeat, net separation of careers and each his job "I am not able to judge the therapy, I judge the people with whom I have a relationship (P-06)

... and so, once they discovered diabetes, they told me what therapy to do, the insulin ... I accepted without problems, also because I am a peasant ... I was not worried ... (P-09)

Accepting as test

Respondents consider the treatments offered a test to be performed, from the moment they are unable to translate the treatment into experiential terms, both from the point of view of the effectiveness, the experience, and the potential consequences.

what Dr. XXX proposed to me was fine for me. From the moment we understood what it was, with name and surname, I decided to try and start the therapy. (P-04).

... since my illness is practically rare, I accept what they give me, in the hope of finding the right one, which is right for me ... (P-14).

Substituting the other one

In this conceptual category, participants tend to replace each other. In both cases, both on the physician's and the patient's side, there are factors that lead to the setting aside of the relationship, in favour of an invasion of the field against the other participant in the process. In this category, regarding healthcare professionals, emerging that physicians are inclined to replace the patients when, despite the presence of a potential therapeutic option, they decide not to propose it to the patient.

Knowing in advance the impact of the treatment

From the analyzed data it emerged that physicians decide not to propose a treatment to a person, as it considered as "futile" a treatment of which it reports to know a priori the impact that it could have on the health and quality of life of the patient, also taking into account the cost of the therapy itself.

I happened to decide not to propose it. I'm talking about a case in which this person practically had very little chance of making it, while his condition was bad enough, so I wasn't sure I could help him, as we ran the risk of having him die in therapy ... (HCP-19)

even in the presence of certain severe infectious pictures, I do not propose or implement antibiotic therapies which I consider futile. For example, it has happened to me many times, but it seems to me to be correct, in the sense that, that is what it is the natural development of the disease, I know a priori that antibiotic therapy will not change the prognosis in terms of days or the quality of life of the patient and therefore, often they are very demanding therapies from the point of view of finding veins, of the load of infused liquids, of the potential side effects and also of the cost of the drugs, which I have to tell you, often even the cost affects me, but I also think of others when reasoning on futility is done, because it is not just a matter of indication or clinical reasoning ... (HCP-18)

... it is not proposed when you feel that what you are doing has absolutely no chance of being useful, okay? Useful is not futile but it is very similar to it ... mmm at that moment it may make sense not to propose a treatment, even an expensive one, if the patient's prospects for recovery, that is, if the patient's prospects are real and irrefutable, and in the short term not it makes sense, every

obstinacy can be useless ... post-operative treatment, for example, a patient who links a series of complications, which has become weak, at a certain point it may make sense to pull the oars into the boat and accompany it ... (HCP-21)

Questioning the effectiveness of a treatment

In other cases, the proposal for treatment does not take place, from the moment in which the practitioner doubts the efficacy of some treatments, asserting their lack of effectiveness, questioning the pharmaceutical industry and scientific evidence.

there are therapies that I think are of no use, that is often put on the market but are not really effective, although there are studies to demonstrate their effectiveness ... I think of some drugs that are used for weight loss, or some statins, and hence, I happen not to propose ... (HCP-20)

some drugs, I do not even understand why they are on the market, and I avoid proposing them, that is, they must ask me and convince me ... Let's face it, sometimes it's a matter of the market, but mostly because in the end I'm I have to justify myself if it doesn't work. And so, if I don't think it works, on that person, I don't prescribe it, but I don't even propose it ... (HCP-12)

Suspending to try

In the case in which the patient decides to suspend treatment after experiencing the drug is represented. Patients decide to suspend the treatment on his own, considering the decision a test to be carried out to understand the real the effect of the treatment, even if he has no objective reasons to question the treatment.

this a thing of mine, I'm not sure I'm right, in fact, I do tests ... in fact, the last time we went there ... in the end, I accepted, then instead ... (P-08)

and so, in the end, I didn't do it anymore, let's say I did a test, and then I no longer fell ill with flu, so I think I did right (P-10)

Considering the treatment as dangerous

In other cases, after taking the drug and therefore having a subjective knowledge of the treatment experience, the patients reported that they considered it harmful to their health, and therefore decided to stop taking it, or because they were aware of the experiences of other people, reporting that this led them to consider treatment dangerous, with a consequent loss of meaning.

... I always take the pills, but sometimes I feel sick and I don't take them ... Other times, even here, when I'm hospitalized, I tell the nurses that I don't want the drip because it hurts me, even while injecting it ... (P-13)

the problem is that I had difficulty coughing and expectorating, and I couldn't resist ... a drug for me must make you feel good, don't make you feel bad, otherwise what drug is it? (P-15)

but it is not said that all the time doctors take us because I saw that last year there was a cousin of mine who also came to make injections ... mmm ... he did more than me ... but I don't know exactly, but he had also some leukemia ... well then ... and then they even gave him drips ... but now he's already dead! so why did you do those things there? eh! 7-8 months went and before he came to the hospital to make injections, he did more than me and he was there, after 2-3 months I saw him in a wheelchair and then he is dead! and so why did you give him those medicines there? so he died the same! (P-02)

...yes, it was true that I did the vaccination, but then after seeing those consequences, I preferred to suspend, also because with the work I do I think I made myself antibodies, what's the point? (P-12)

Being convinced on personal beliefs

Moreover, from our interviews, it emerged that personal beliefs are also involved in the patient suspension of treatment, without an apparently logical motivation, but because of a knowledge acquired in his own cultural setting, never questioned by the participant.

... according to the stories of 30 years ago that I heard, from 45 - 65 to 70 years, who is born with the disease is a thing and, does not go away anymore. Instead, it affected me after 45 years up to 70 years, and then according to what I knew it disappears. It goes away, at 70 years of age diabetes disappears. For that I have not taken any medicine for more than 2 years, I decided to interrupt according to what they told me long ago ... I am 70 years old I no longer have diabetes, it returns to normal ... that's why I interrupted with insulin (P-09).

Avoiding the conflict

In this case, after the patient had had the opportunity to experience the treatment, it emerged that the factors that lead the participants to adopt strategies aimed at circumventing the conflict with the other participant in the process come into play in the physician-patient relationship, actually removing the possibility of maintaining an honest and constructive relationship.

Avoiding difficult communications

In the case of the healthcare professional, once the perspective of treatment has been framed, it is possible that the possible therapeutic solutions come into play, and that they are proposed, in order to avoid having to face a difficult communication with the patient.

... you have to put together so many things ...! To do ... And then it's not easy! I tell you for a doctor to recognize the futile, that is that the treatment has become futile, that is no longer useful, I tell you, in my opinion, one of the most difficult things! Why then force him to have to say, to have to tell him the patient! And it's not an easy communication! (HCP-02)

... from the moment I say, "I have to close", the patient begins to ask questions: "How much remains for me to live? What should I do "? ... which are heavy questions, no! They are onions, hard to swallow! Eh, While instead if you say "look, we also have this ..." The patient, he clings to you! No? He is not there to ask you then I will die. He says "he gave me another thing, I cling to the last hope" (HCP-19)

Adopting a technical approach

In cases where the prognosis is clear, although it is difficult to recognize the clinical picture among professionals, it happens that an alibi is unconsciously constructed to avoid the burden of the conflict through the adoption of a highly technical approach, and consequently less demanding from the point of view of the report.

... it was difficult even to declare between health professionals that there was no therapeutic chance because he did not have a cancer diagnosis. And no, he had this diagnosis of severe stage kidney failure, but there was not a very serious vasculopathy on all the various peripheral sectors. So it was known that something would have happened that would have worsened and we knew that he

did not have a very long survival but had never been explicitly declared either to him or to his sister ... ... "When the leg wound improves, let's talk about back to home". So much so that our first meetings were about what kind of wheelchair to ask at home and we were organizing the discharge in reality, then the exams were not going well and the dehiscence ... (HCP-14)

... at that moment, my defense mechanism, is to try to reassure and try to manage the symptom, it is part of our category, mmm... of and moving on the technique and then doing technical things on the patient ... then all this was shared mmm, between us, I repeat and I underline it in the very, very, very heavy way ... (HCP-15).

Information forcing

In cases in which patients have requested the suspension of a drug, it has emerged that the physician is inclined to implementing an information-forcing, in which both the potential risks and the potential benefits are addressed but, from the relational point of view, forcing the patient to decide for himself.

I explained to him and I said "look, if we suspend, we get worse and get worse quickly and, when we get worse, it makes no more sense to resume therapy because it doesn't work anymore" ... " you don't go back" ... I was also very, very too mmm, a little even brutal perhaps, however, I wanted to make him understand that if he suspended ... I told him, "maybe his illness remains like this for other 4, 5, 6 months I don't know, maybe not! maybe in two months, we find ourselves a disease frankly worsened and after ... no turning back eh ... of this disease, one dies! ". So ... I wanted this thing to be very clear here, and he said to me "Yes, yes, yes well! Anyway, one dies the same, mmm, no, I don't want therapy anymore " (HCP-01)

Owning the truth about the proven treatment

With regard to the patient, from the collected data it emerged that the patient, once a treatment has been agreed, can decide to suspend it, believing that he is in possession of the truth in the first person about the effects it has on himself, avoiding to involve and above all to open conflict with the physician.

since I started that treatment, the side effects were more of the benefits and me who already have my illness ... well ... I started to decrease and then I stopped altogether (P-05)

I at the end, noticed that he was giving me that problem, even though the doctor had reassured me that on a sexual level things would not change, and then slowly, let's say, I started "forgetting" to take the tablets (P-16)

Moreover, in light of a health condition considered to have not improved, which led to scepticism, the patients reported that they had arrived at the decision to suspend treatment without involving the physician, discrediting the physician and the agreement reached previously.

... let's try ... there was a doctor there from Bologna ... I don't know ... so ... they too do ... I also don't agree much to do ... they say ... the guinea pig ... after they had to stop because I went to Reggio Emilia and in the emergency room ... my son brought me ... "tell him to stop doing that therapy there" ... they said so (P-02)

look, since the surgeon didn't listen to me, in the end, I suspended and I'm trying a different treatment ... I didn't talk to the surgeon, I just changed the physician, and he changed me the drugs (P-15)

I'm not sure who knows what kind of relationship with my neurologist, she's often absent and I had difficulty getting in touch with her ... the fact is that the side effects were really too heavy, the *tingling in my legs had become unbearable. I couldn't walk because of pain, and so I finally decided to stop taking those pills. I told my parents and I was fine at first, then I felt sick.* (P-14).

Leaning on other confirmations

The interviews also showed that when patients find themselves looking for other answers/confirmations regarding the decision to suspend treatment, some factors can be activated that lead them to adopt strategies that lead them to avoid facing the interaction with the physician.

Then when I arrive in the ward and the doctor wants to give me that drug since I don't want to take it, I say yes to the doctor on duty, so I know that Dr. XXXX passes in the morning, he knows what I think and changes my therapy (P-03)

in the end seeing all those cases of pneumonia that arrived, despite the vaccination, I began to talk about it with colleagues and to convince myself that it was not so effective, but it is not that I went to someone, I simply failed to repeat the vaccination ... (P-10)

Being emotionally involved

In this conceptual category, it emerged from our data that emotional factors are also involved that lead the process participants to turn away the relationship away from the physician-patient interaction. The physician, faced with a suspension of treatment decided by the patient, can see that his role is lost, feeling subjugated, defeated, losing control of his part regarding the therapeutic relationship. The patient, instead, not finding an adequate answer to his problem, reports a sense of incompleteness, while in the case in which the evaluations are carried out based on the experiences of others, he may feel afraid because of the consequences attributed to the treatment.

Feeling unrecognized

From the collected data it emerged that physicians feel a sense of fear of not being recognized in their own role, that lead to believe the relationship to be a complex obstacle to overcome, also when the patient challenges his own skills and competences, up to adopting a counterproductive position, which removes the objectives for which one has entered into a relationship with the patient.

Anyway, there was no way, when you see fanaticism, that is, the, the ideological position, I struggle a lot. In fact, it's not that I lost my temper but, I put myself in a position of contraposition (HCP-21)

I find it hard to think that I have to see them again on Monday, because I already know that it will be a good battle, I hope that the exams go better but I already know that it will be a good battle, in which she asks me "why does she do nothing?", for me the problem is the toxicity in the face of the benefit of the treatment that I don't feel sure to propose (HCP-19)

Feeling subjugated/discredited

From our data, it emerged that professionals feel subjugated, even discredited, when patients decide to suspend drug treatment, or when patients, after a non-shared suspension, have relapses and return to the caregiver with the need to be treated again from them.

So this is a drama for me. Because you see that there is a position already assumed and not, do not pass! Don't pass! Very rare, that is, one happens to me every 4 years, but ... these things are mortal!. (HCP-02).

... then the problem arises when they return after having suspended again, obviously after a relapse ... You understand well that it is hard to hold back, then obviously you try to keep calm ... But the desire to say "I told you about don't suspend!" there is always. (HCP-09)

Feeling defeated

In this context, it also emerged that, from the moment a patient decides to suspend the treatment of choice, previously agreed upon and tried on his own skin, the professional must deal with the sense of defeat/powerlessness due to the impossibility of transmitting the importance of treatment to the patient.

at that moment I felt a bit helpless, in the sense that, I wanted him to pass the…. my point of view! yes! I wanted to pass on to him my point of view, with strength, but, he did not pass. He understood, why he is not stupid but he understood the things I told him, I wrote them to him, I told him, I repeated them to him in front of his son, I'm sure he understood very well ... mmm, however, at that moment there he was fixed on his position and not, mmm there was no way of moving him... of a centimeter (HCP-01)

ah yes yes, in the end, it went like this, he came and told me. Of course it's a hard thing to digest, I honestly didn't agree, but in the end, despite the attempts, after explaining everything well, what else could I have done? (HCP-10)

Feeling of incompleteness

From the interviews, it emerged that the patients interviewed are projected towards the search for certain answers, given that due to a treatment experienced in the first person and that leads to discomfort, there is a strong sense of incompleteness, a factor that which turns out to be important in the decision to intake of drug treatment.

I'm down in this period, also because every time there is a proposal, every time a problem to face, every time I have to hope that things go better, but it's not like that ... I understand that my condition is complex, but believe me, this game is really stressful, I can't take it anymore ... (P-08)

I end up looking for therapy for my illness, and this doesn't happen. Every time I find myself trying drugs, that one was effective, let's say, but it gave me too much pain ... the point is that I wish there was a solution, a cure, not continuous proof ... (P-14).

Being scared of suffering by the consequences of treatment

Patients also reported that experiences lived by others, led them had to face with the fear of suffering because of the consequences of the treatment and that this factor was important in the subsequent decision of suspending the treatment in question.

my mother had a heart attack a few days after she was vaccinated against the flu, and there was suspicion, I stopped doing it since, I don't know if that was the cause, but I prefer not to do it anymore. (P-11)

Discussion

All the main categories of our study have led to the emergence of the concept that, if in the interpersonal interaction between patient and physician, a discordant therapeutic relationship is established, various factors are activated converting the goals of the therapeutic relationship into something different from the motivation for which it itself had been activated.

Our theoretical model explains how healthcare interactions influence, and are influenced by, the way that people relate to one another. Particularly emerged how delicate the physician-patient relationship is, and what implies neglecting it, both on the part of the physician and the patient. Indeed, authors agree that therapeutic interpersonal relationships between health care professionals and patients are associated with improvements in patient satisfaction, adherence to treatment, quality of life, levels of anxiety and depression, and decreased health care costs (45 - 47). While instead, when a discordant therapeutic relationship is established, a door opens to various factors that, in the case of loss of sense of treatment, come into play, resulting in behaviors that divert the reason why the physician and the patient entered into the report, as also reported by Step, Rose, Albert, Cheruvu, & Siminoff (46), who stated that negative physician-patient relationships, lead to an increased of psychological distress and feelings of dehumanization.

From the moment in which a discordant therapeutic relationship is established, a door opens to various factors that, in the event of loss of sense of treatment, come into play, resulting in behaviors that divert the reason why the physician and the patient entered into report. In fact, with regard to the prospect of suspension (or non-proposal by the physician) of drug treatment, the conflict (in a positive sense, in a constructive relationship) that ensues, is considered as an obstacle from which to escape at the level relational, instead of being taken as an opportunity to establish a trusting and honest relationship between the participants in the process.

Differently from what reported by Bell, Airaksinen, Lyles, Chen, & Aslani (48), that with regard to concordance, they argued that a consultation between a physician and a patient is a negotiation; and with what is stated by Dickinson, Wilkie, & Harris (49), according to which the loss of meaning of treatment can take place through a concordant process; from our theory, emerged that are involved determining factors in the therapeutic relationship, that put at risk the relational process, jeopardizing the quality of the assistance and patient satisfaction. Indeed, according to Larson, Sharma, Bohren, & Tunçalp (50), satisfaction with care is inherently shaped by an individual's values, expectations, and experiences, such as expecting to have a health-care professional who includes them in decision-making and thus is a highly subjective measure requiring a nuanced approach to its interpretation, considering moreover that an involving and constructive relationship has an important role to improve patient adherence with treatment (51).

From the emerged theory, the one in which the proposal of treatment by the physician takes place and the consequent acceptance by the patient, or where the curator reserves the right not to propose a treatment of choice, some factors emerge that compromise the success of a therapeutic relationship. Essentially, in the first case it happens that between the physician and the patient, at the time of the proposal and the acceptance of pharmacological treatment, they are inclined not to effectively negotiate the object of the contract. In effect, both in the article of Aranson (52), such as in the Meta-syntesis conducted by Cullinan, O'Mahony, Fleming, & Byrne (53), in which emerge that physicians need to please the assisted person in prescribing drugs, and that they the fact that physicians sometimes feel forced to prescribe; from our theory emerged that the physicians are projected towards the need to offer a solution and to satisfy the requests in terms of improving the patient's state of health. However, and differently from what reported in the study of Cullinan, O'Mahony, Fleming, & Byrne (53), in which emerge the tension between experience-based prescriptions and guidelines, and the fear felt in the act of prescription, from our data emerge that physicians feel sure of his role, and supported by scientific evidence, what brings them to omits the patient's feedback.

As for patients, Marant, et al. (54) stated that acceptance is the results of the balance between benefits (advantages) and risks (disadvantages) of treatment, as rated by the patients based on their own personal experience of their treatment. Furthermore, Curtin & Schulz (55) added that the basis for risk-benefit assessment is the balance between the benefits of treatment, such as its therapeutic efficacy, and the perceived risks of this treatment, such as adverse events and treatment constraints. However, and in harmony with what expressed by Aronson (52) and Lambert, Checkroun, Gilet, Acquadro, & Arnould (56), from our theory emerge that the perspective of the patient is not necessarily the same as that of health care providers, since not having had the experience of treatment, patients turn out to have no elements for the evaluation of the proposal made by the physician, and tend to accept in an uncritical way, delegating his health to the physician, accepting the treatment as a test. In this framework, emerge both a paternalistic approach by physician, and patient compliance, as described in the position paper produced by the European Patients Forum (57), in which patient beliefs are not interacting in this process or are seen as an obstacle to treatment, while the patient acceptance is based on the physicians' status.

While in the second case, where physicians opt not to offer the treatment, other factors come into play, such as considering treatment as futile, referring to the impact it will have on the health and quality of life of the patient, and the cost of the treatment, in agreement to Sibbald, Downar, & Hawryluck (58) and Bahramnezhad et al. (59), which lead professionals to make not negotiated decisions with the patient.

From the collected data emerge instead of the factors that come into play after the patient has started the treatment, and he has tried it on his own skin. In the case that the patient once the treatment has been tried replaces itself the physician, the factors that emerge from our theory indicate that at the time of acceptance, the proposed treatment is considered a test, and then not adhered as agreed; that if the treatment is considered harmful by the patient, he may decide to suspend without consulting with the physician; or that factors such as negative experience experienced by others, which confirms the patient's impressions, or that a factor such as personal beliefs is involved in the decision to suspend the drug are implicated. On this aspect, it is worth noting that the present literature is poor and focused on people who are being treated by mental care services (60 - 62); which brings out the need to increase the level of empirical knowledge on this phenomenon.

Moreover, although conflict between physician and patient is considered inevitable (63), hat people disagree should be seen as a healthy and integral part of human interaction, and that most everyday problems are resolved simply and easily by the people involved, and that while those problems that are not dealt with and end up escalating into something that interferes also with a practitioner’s professional life (64), from our data result that, once a non-constructive relationship is activated, factors that influence the process emerge and push the participants to avoid conflict. In the case of the physician, it is present when adopting a possibilist approach, aimed at avoiding difficult communication with the patient; in cases where the physician, after requesting the suspension of a drug, adopting a paternalistic approach, leaves the patient alone to decide; or in cases where once an unfavorable clinical picture has been identified, a technical approach is adopted aimed at avoiding the relationship with the patient. Furthermore, factors have emerged that lead the patient to circumvent the conflict, and to suspend treatment, bypassing the conflict with the patient. In this case, patients discredit the physician, seeing no improvement in their condition; if the patient is considered to be the true connoisseur of the effects of the drug; or in the event that they try to find other answers/confirmations concerning the treatment. In this context is possible to note, in agreement to Ury (65), and that HCPs are not alone in avoiding conflict, that most people fear conflict and do their best to keep out of it and away from it, despite the fact that conflict is an inevitable factor in our daily personal and professional lives.

In our theory, it emerged how emotional factors are implicated in therapeutic discordance. Emotions can play a significant role in human interactions, yielding communicative intentions, modelling behaviour, influencing information processing, and also determining choices (66). A qualitative study conducted by Yedidia (67), emerges that physicians may be less prone to emotional involvement, as this could undermine their autonomy and destabilize the consumer-provider relationship. By our data analysis, in the case of physicians, when a patient decides to suspend treatment, emerge the fear that they are not recognized in their role, they feel subjugated, discredited, and having to must come to terms with the sense of powerlessness that this decision produces in them. However, these factors tend to remain unexpressed by physicians. This, in according to Ely, Levinson, Elder, Mainous, & Vinson (68) and Lipschitz, Maltsberger, Haas, & Wynecoop (69), can lead to an impede the use of patient-centred skills and also can lead with harmful behaviours, such as inappropriately interrupting the patient, changing the subject, avoiding patients' psychological issues, avoiding bonding with patients to prevent suffering, avoiding conducting certain medical procedures again, or avoiding patients altogether. While with regard to the patient, the decision to suspend may be influenced by factors such as the fear of the consequences of the treatment; or because of the sense of incompleteness that gives rise to a treatment that brings with it some inconveniences in everyday life, things that are not expressed to the carer, thus compromising a constructive relationship. Indeed, in according to Eide, Frankel, Bull Haaversen, Vaupel, Graugaard, & Finset (70), there is evidence that patients are hesitant to raise emotionally laden.

Conclusion

The emerging theory comes into dialogue with some concepts already investigated and otherwise conceptualized. Indeed, to keep up with the times, medicine has spawned a lexicon of terms that are in continuous evolution regarding the complex process of medication-taking behavior of patients (71). The evolution of the terms "compliance", "adherence" and "concordance" in the field of medicine-taking represents a good example of this. Although in line with the main objective of giving meaning to the process of sharing decisions concerning drugs, these three terms are frequently used interchangeably generating some confusion. Compliance, adherence, and concordance mean different things and must be used in different ways (72), from the moment in which they were conceived in different times, methods and purposes.

Compliance and adherence belong to a paternalistic medicine concept (73). Instead, concordance implies an agreement about the therapeutic regimen that the patient will follow, made between the prescriber and patient and therefore belong to a less-paternalistic concept, with the aim of enhancing the relationship between the prescriber and their patient. And this concept is in line with the World Health Organisation has long held that patients and health professionals have a right (and a duty) to participate in the delivery of health care (74). Moreover, according to De Las Cuevas (72), concordance could be useful as a normative or aspirational term, while compliance and adherence must be the terms used for scientific measurement in the medicine-taking field. Although none of these terms are ideal solutions to understanding the complex process of medication-taking sharing between physicians and patients, the move from compliance to adherence and concordance represents genuine progress in this field, which puts the patient’s perceptions at the center of the whole process (71).

Therapeutic discordance theory is part of the concordance debate, highlighting the implicated factors that bring to light a negative result of the relational process between physician and patient.

People using health services are increasingly asking for more responsive, open and transparent health care systems. They expect practitioners to engage them in the decision-making process, although individual patients may vary substantially in their preferences for such involvement (17). However, as emerged from our theory, if the relationship is neglected, all these good intentions can remain obscured, yielding, from a process born of a need for health, a new problem to be faced both for the patient, for the physician, but also for the community.

Furthermore, from our theory it emerges that medical futility, with regard to the drug sharing process, is a non-negotiated process, which belongs to the medical team, which a priori decides whether or not to propose a drug, based on its own assessments, completely changing the perspective and value of a concordant process, carried out together with the patient.

Implications for clinical practice

Therapeutic discordance in the loss of meaning of a pharmacological treatment begins when the physician and the patient interact neglecting the relationship, through a non-negotiated process of proposal and acceptance of the treatment. To address this issue, it is necessary that organizations offer to healthcare professionals relational skills that reassure them and facilitate patient involvement when the possibility of a therapeutic option is envisaged. In this training process, the need to deal issues such as emerges methods to effectively involve people in therapeutic choices, strategies to increase the level of listening and understanding of the person's desires throughout all the interpersonal interaction between patient and physician, the positive value of the conflict in a truthful relationship, the possibility of trusting in support relational services in case of loss of control of the relational process. Strategies for promoting an active role for patients should pay attention to health literacy, shared decision-making and self-management.

When the person decides to suspend a treatment, it may be necessary adopt a relational approach aimed at to have a clear understanding of why the patient made this decision (for example worsening health, specific treatment problems, depression) in order for them to determine if there are any improvements that can be made that could affect the patient' decision. Furthermore, it could be useful to involve other professionals, such as social worker and nurse, and if the patient wishes, also involve family members, to speaking with the patient and will encourage it to talk openly about own feelings and reasons. At this particular time for the patient, and in order to maintain an honest and truthful relationship, it is good to reassure the person that the relationship with physicians will not be affected by his decision.

Understanding the emotional factors that come into play in physicians when a person decides to suspend opens the door to developing tools to facilitate their understanding and support them in these situations. The strategies to recognize and face these issues can be provided through training sessions that place the focus on the physician's relationship in a person-centered care relationship.

The emerged knowledge of the factors involved in the therapeutic discordance can be useful to spread in training courses for physicians and medical students, a category that is often "accused" of neglecting the relational aspect, but at the same time, sees in training programs a strongly biomedical, centered imprint on illness, and not centered on the person, family and society.

In order to improve the application and evaluate the need for implementation of innovative strategies, it is critical that continue to build a meticulous body of work that extends existing evidence and demonstrates the significance of a relational approach patient-centered and its importance to improving processes involved in decision-making by citizens who access health services.

Auto evaluation

During the development of the study, a large margin-left to participants regarding the guidance of the research process. The theoretical construction was generated, starting from the meanings that the participants gave to the phenomenon studied. The explanation of the theory emerged through the voice of the participants.

During the different phases of the study, the principal researcher (MEDC, RN, PhD student) wrote his own observations and his own reflexivity, the criteria used in constructing his own way of thinking, so as to better understand how he was developing the theory and removing his pre-concepts as much as possible regarding the object of study. Furthermore, the constant comparison with the research coordinator (LG, Qualitative Research Methodologist), allowed the principal researcher to observe the construction of the emerging theory through a different lens.

Although the literature is rich in examples in which other participants in the decision-making process play an important role, the theory that emerged enters the debate on concordance, a topic that concerns the relationship between physician and patient. This that could see as a restraint, open the doors to broaden the results of the study, through the creation of a study, with a suitable research question, which allows giving voice to caregivers and other health professionals (nurses, physiotherapists, etc.) and family members/caregivers.

The theoretical sampling was conducted based on the reasoning that emerged from the data reported by the participants. The sampling has been extended to different contexts of assistance and care, to offer a broad view of the phenomenon studied. The data was considered sufficient to support the inferences produced.

The emerged theory is the result of a rigorous collection and analysis of data and presents itself in the form of factors collected in conceptual categories, and not in the form of a process. This modality of presentation is due to the complexity of the phenomenon studied, the variety of contexts in which the research took place, which involved an articulated interpretative researchers' approach.

The core category can put together the meaning of what the research participants have reported. Conceptual categories are linked together under the core category and represent the explanation of the different ways of activating the factors that emerge when the relationship is neglected by the participants in the process, denoting a negative process from a relational point of view.

The categories that emerged are significant, are integrated into the current debate and offer new perspectives for the development of further investigations and application in daily clinical-organizational practice, suggesting ways for positive change in the context of assistance and care.

Being a qualitative study, conducted in a multicenter context within an Italian province, it is possible to state that the emerged theory is robust and full of explanatory cues, however the results that have emerged must be addressed and interpreted based on the context in which it was conducted, taking into account the different nuances aside, and the aspect of modifiability typical of the results of qualitative research.

References

1. Mullen, P. D. (1997). Compliance becomes concordance. BMJ (Clinical Research Ed.) , 691-2.

2. Viswanathan, M., Golin, C. E., Jones, C. D., Ashok, M., Blalock, S. J., Wines, R. C., et al. (2012). Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review. Annals of Internal Medicine , 785-795.

3. Ho, P. M., Bryson, C. L., & Rumsfeld, J. S. (2009). Medication adherence: its importance in cardiovascular outcomes. Circulation , 3028-35.

4. Fraser, S. (2010). Concordance, compliance, preference or adherence. Patient Preference and Adherence , 95-96.

5. daCosta DiBonaventura, M., Copher, R., Basurto, E., Faria, C., & Lorenzo, R. (2014). Patient preferences and treatment adherence among women diagnosed with metastatic breast cancer. American Health & Drug Benefits , 386-96.

6. National Center for Health Statistics. (2016). With Chartbook on Long-term Trends in Health, USA. Hyattsville, MD: Health.

7. Osterberg, L., & Blaschke, T. (2005). Adherence to medication. The New England journal of medicine , 487-97.

8. Neiman, A. B., Ruppar, T., Ho, M., Garber, L., Weidle, P. J., Hong, Y., et al. (2017). CDC Grand Rounds: Improving Medication Adherence of Chronic Disease Management - Innovations anc Opportunities. MMWR Morb Mortal Wkly Rep .

9. Peterson, A. M., Takiya, L., & Finley, R. (2003). Meta-analysis of trials of interventions to improve medication adherence. American Journal of Health-System Pharmacy , 657-65.

10. Gottileb, H. (2000). Medication nonadherence: finding solutions to a costly medical problem. Drug Benefit Trends , 57-62.

11. World Health Organization (2003). Adherence to long-term therapies: Evidence for action. Achieved on August 19, 2019 from https://apps.who.int/iris/bitstream/handle/10665/42682/9241545992.pdf;jsessionid=3BB95C8FC19B9E553F241184729A4599?sequence=1

12. Kaba, R., & Sooriakumaran, P. (2007). The evolution of the physician-patient relationship. International Journal of Surgery , 57-65.

13. Edelstein, L. (1937). A history of medicine. Archives of internal medicine .

14. Parsons, T. (1951). The social system. New York: Free Press.

15. Szasz, T., & Hollender, M. H. (1956). A Contribution to the Philosophy of medicine. The Basic Models of the Doctor-Patient Relationship. JAMA International Medicine , 585-592.

16. Emanuel, E. J., & Emanuel, L. L. (1992). Four Models of the Physician-Patient Relationship. JAMA , 2221-2226.

17. World Health Organization. (2016). Patient Engagement: Technical Series on Safer Primary Care. Geneva: World Health Organization.

18. Lown, B. A., & Victor, K. E. (2018). Should a Physician Offer Recommendations Based on Experience but Contrary to Current Practice Guidelines? AMA Journal of Ethics .

19. Eysenbach, G., & Jadad, A. R. (2001). Evidence-based Patient Choice and Consumer health informatics in the Internet age. Journal of Medical Internet Research .

20. McMullan, M. (2006). Patients using the Internet to obtain health information: How this affects the patient–health professional relationship. Patient Education and Counseling , 24-28.

21. Hibbard, J. H. (2017). Patient activation and the use of information to support informed health decisions. Patient Education and Counseling .

22. Hibbard, J. H. (2009). Using Systematic Measurement to Target Consumer Activation Strategies. Medical Care Research and Review .

23. Tonelli, M. R. (1998). The philosophical limits of evidence-based medicine. Academic Medicine , 1234-40.

24. United Nations. (1948, December 10). Universal Declaration of Human Rights. Tratto il giorno July 07, 2019 da United Nations: https://www.un.org/en/universal-declaration-human-rights/

25. Sulmasy, D. P. (2013). The varieties of human dignity: a logical and conceptual analysis. Medicine, Health Care, and Phiosophy , 937-44.

26. World Health Organization. (2019). Patient's rights. Achieved on July 04, 2019 from World Health Organization: https://www.who.int/genomics/public/patientrights/en/

27. Abedi, G., Shojaee, J., Moosazadeh, M., Rostami, F., Nadi, A., Abedini, E., et al. (2017). Awareness and Observance of Patient Rights from the Perspective of Iranian Patients: A Systematic Review and Meta-Analysis. Iranian Journal of Medical Sciences , 227-234.

28. Murgic, L., Hébert, P. C., Sovic, S., & Pavlekovic, G. (2015). Paternalism and autonomy: views of patients and providers in a transitional (post-communist) country. BMC Medical Ethics .

29. Rashid, M. A., Edwards, D., Walter, F. M., & Mant, J. (2014). Medication Taking in Coronary Artery Disease: A Systematic Review and Qualitative Synthesis. Annals if Family Medicine , 224-232.

30. Sabadosa, K. A., & Batalden, P. B. (2014). The interdependent roles of patients, families and professionals in cystic fibrosis: a system for the coproduction of healthcare and its improvement. BMJ Quality & Safety , 90-4.

31. World Health Organization, Regional Office for South-East Asia. (2013). Strengthening the doctor-patient relationship. India: SEARO Publications.

32. Blumer, H. G. (1954). What is wrong with social theory? American Sociological Review , 3-10.

33. Charmaz, K. (2014). Constructing Grounded Theory. 2nd edition. London: SAGE.

34. Glaser, B. G., & Strauss, A. L. (1967). The Discovery of Grounded Theory: Strategies for Qualitative Research. Chicago-New York: Aldine de Gruyter.

35. Todres, L., Galvin, K. T., & Holloway, I. (2009). The humanization of healthcare: A value framework for Qualitative Research. International Journal of Qualitative Studies on Health and Well-being , 68-77.

36. Sasso, L., Bagnasco, A., & Ghirotto, L. (2016). LA RICERCA QUALITATIVA. Una risorsa per i professionisti della salute. Milano: Edra S.p.A.

37. Creswell, J. W. (2009). Research design: qualitative, quantitative, and mixed methods approaches. Thousand Oaks: Sage Publications.

38. Given, L. M. (2008). The SAGE Encyclopedia of Qualitative Research Methods. SAGE Publications, Inc.

39. Spradley, J. P. (1979). The ethnographic interview. Orlando: Harcourt Brace.

40. Strauss, A., & Corbin, J. (1998). Basics of qualitative research: Techniques and procedures for developing grounded theory. Thousand Oaks, CA: SAGE.

41. Morse, J. M. (2015). Critical Analysis of Strategies for Determining Rigor in Qualitative Inquiry. Qualitative Health Research .

42. International Council of Harmonisation. (2016). Guideline fo Good Clinical Practice. Achieved on 07 14, 2019 from ICH: https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

43. World Medical Association. (2013). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA , 2191-4.

44. Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews. International Journal for Quality in Health Care , 349-357.

45. Ferrell, B. R., & Dean, G. E. (1994). Ethical issues in pain management at home. Journal of Palliative Care , 67 - 72.

46. Step, M. M., Rose, J. H., Albert, J. M., Cheruvu, V. K., & Siminoff, L. A. (2009). Modeling patient-centered communication: oncologist relational communication and patient communication involvement in breast cancer adjuvant therapy decision-making. Patient Education and Counseling , 369-78.

47. Kelley, J. M., Kraft-Todd, G., Schapira, L., Kossowsky, J., & Riess, H. (2014). The influence of the patient-physician relationship on healthcare outcomes: a systematic review and meta-analysis of randomized controlled trials. PLoS One .

48. Bell, J. S., Airaksinen, M. S., Lyles, A., Chen, T. F., & Aslani, P. (2007). Concordance is not synonymous with compliance or adherence. British Journal of Clinical Pharmacology , 711-3.

49. Dickinson, D., Wilkie, P., & Harris, M. (1999). Taking medicines: concordance is not compliance. BMJ , 787.

50. Larson E., Sharma J., Bohren M.A. & Tunçalp Ö. (2019). When the patient is the expert: measuring patient experience and satisfaction with care. Bulletin of the World Health Organization, 563-569.

51. Kelly M., McCarthy S., Sahm L.J. (2014). Knowledge, attitudes and beliefs of patients and carers regarding medication adherence: a review of qualitative literature. European Journal of Clinical Pharmacoly, 1423-31.

52. Aronson, J. K. (2007). Time to abandon the term ‘patient concordance’. BJCP , 711-713.

53. Cullinan S., O'Mahony D., Fleming A., Byrne S. (2014). A meta-synthesis of potentially inappropriate prescribing in older patients. Drugs & Aging, 631-8.

54. Marant, C., Longin, J., Gauchoux, R., Arnould, B., Spizak, C., Marrel, A., et al. (2012). Long-term treatment acceptance: what is it, and how can it be assessed? Patient , 239-49.

55. Curtin, F., & Schulz, P. (2011). Assessing the benefit: risk ratio of a drug--randomized and naturalistic evidence. Dialogues in Clinical Neuroscience , 183-90.

56. Lambert, J., Checkroun, M., Gilet, H., Acquadro, C., & Arnould, B. (2018). Assessing patients’ acceptance of their medication to reveal unmet needs: results from a large multi-diseases study using a patient online community. Health and Quality of Life Outcomes.

57. European Patients Forum. (2015). Adherence and Concordance EPF position paper. Brussels: European Patients Forum.

58. Sibbald, R., Downar, J., & Hawryluck, L. (2007). Perceptions of “futile care” among caregivers in intensive care units. Canadian Medical Association Journal , 1201-1208.

59. Bahramnezhad, F., Cheraghi, M. A., Salsali, M., Asgari, P., Khoshnava Fomani, F., Sanjari, M., et al. (2014). Futile care; concept analysis based on a hybrid model. Global Journal of Health Science , 301-307.

60. Souto Melo, A. P., & Crosland Guimarães, M. D. (2005). Factors associated with psychiatric treatment dropout in a mental health reference center, Belo Horizonte. Brazilian Journal of Psychiatry .

61. Olfson, M., Mojatbai, R., Sampson, N. A., Hwang, I., & Kessler, R. C. (2010). Dropout from Outpatient Mental Health Care in the United States. Psychiatric Services , 898-907.

62. Minamisawa, A., Narumoto, J., Yokota, I., & Fukui, K. (2016). Evaluation of factors associated with psychiatric patient dropout at a university outpatient clinic in Japan. Patient Preference and Adherence , 1903-1911.

63. Wolf, S. M. (1988). Conflict Between Doctor and Patient. Law, Medicine & Healthcare , 197-203.

64. Marshall, P., & Robson, R. (2019). Conflict Resolution. Achieved on August 19, 2019 from Royal College of Physicians and Surgeons of Canada: http://www.royalcollege.ca/rcsite/bioethics/primers/conflict-resolution-e

65. Ury, W. (1991). Getting past no: Negotiating your way from confrontation to cooperation. New York: Bantam Books.

66. Croskerry, P., Abbass, A., & Wu, A. W. (2010). Emotional influences in patient safety. Journal of Patient Safety , 199-205.

67. Yedidia, M. J. (2007). Transforming Doctor-Patient Relationships to Promote Patient-Centered Care: Lessons from Palliative Care. Journal of Pain and Symptom Management , 40-57.

68. Ely, J. W., Levinson, W., Elder, N. C., Mainous, A. 3., & Vinson, D. C. (1995). Perceived causes of family physicians' errors. The Journal of family practice , 337-44.

69. Lipschitz, A., Maltsberger, J. T., Haas, A. P., & Wynecoop, S. (2000). Therapists' reactions to patients' suicides. American Journal of Psychiatry , 2022-7.

70. Eide, H., Frankel, R., Bull Haaversen, A. C., Vaupel, K. A., Graugaard, P. K., & Finset, A. (2004). Listening for feelings: identifying and coding empathic and potential empathic opportunities in medical dialogues. Patient Education and Counseling , 291-297.

71. Chakrabarti, S. (2014). What's in a name? Compliance, adherence and concordance in chronic psychiatric disorders. World Journal of Psychiatry , 30-36.

72. De Las Cuevas, C. (2011). Towards a clarification of terminology in medicine taking behavior: compliance, adherence and concordance are related although different terms with different uses. Current Clinical Pharmacology , 74-7.

73. Khair, K. (2014). Compliance, concordance and adherence: what are we talking about? Haemophilia: the official journal of the World Federation of Hemophilia , 301-3.

74. World Health Organization. (1977). Primary health care. Geneva: World Health Organisation.