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Faculdade de Farmácia

Pharmaceutical consultation in a hospital setting: the example in oncology at São Francisco Xavier Hospital

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Resumo

Este estudo é um estudo exploratório para caracterizar a comunicação clínica entre o farmacêutico hospitalar e doentes oncológicos no âmbito da consulta farmacêutica hospitalar. Para além disso, e mais especificamente, pretende avaliar o nível de centramento no doente. O conteúdo verbal da comunicação entre o farmacêutico e o doente foi analisado através do Roter Interaction Analysis System (RIAS). Posteriormente, variáveis de comunicação e características humanísticas, como o nível de centramento no doente, foram calculadas. O processo de tomada de decisão, que se relaciona com o centramento no doente, foi avaliado através do OPTION (Observing Patient Involvement in Shared Decision Making). Por outro lado, para abordar a informação terapêutica e a complexidade da comunicação, foi criado um indicador de complexidade, o Therapeutic Information Complexity Score (TICS). Todos os dados foram analisados estatisticamente através do SPSS v26. Este estudo compreendeu 13 consultas de doentes oncológicos, com uma farmacêutica hospitalar. Em 6 consultas o doente foi acompanhado por um familiar. A dominância da fala do farmacêutico foi maior nas consultas diádicas (53,49%; $U = 6,0$, $p = 0,032$). O número médio de questões abertas feitas foi diferente do número médio de questões fechadas ($W = 81,0$, $p = 0,013$). Quanto à relação da conversa psicossocial / biomédica do farmacêutico para o doente, o valor médio da relação (0,09) foi significativamente maior para as consultas com tratamentos que exigem maior conteúdo informativo ($U = 2,00$, $p = 0,023$). O valor médio de centramento no doente foi de 0,31 ($SD = 0,10$), e o valor médio de OPTION foi de 12,69% ($SD = 5,55\%$). Estes resultados mostraram que ainda falta aplicar uma comunicação efetiva e centrada no doente nas consultas farmacêuticas na área da oncologia. As organizações profissionais e de saúde devem refletir sobre a necessidade de preparar continuamente os farmacêuticos hospitalares para a prestação de consultas farmacêuticas eficazes e humanísticas.

Palavras-chave: Comunicação clínica; Cuidados centrados no doente; RIAS; OPTION; Farmacêutico hospitalar; Consultas farmacêuticas; Oncologia

Abstract

This study is an exploratory study to characterize the hospital pharmacist-clinical communication and patient-centeredness in oncological pharmaceutical consultations. The pharmacist-patient exchange was analyzed through Roter Interaction Analysis System (RIAS). Communication variables and humanistic traits, such as patient-centeredness score, were calculated. The decision-making process was evaluated as a patient-centeredness surrogated measure through OPTION (Observing Patient Involvement in Shared Decision Making). On the other hand, to address therapeutic information and communication-complexity, an indicator was deployed, the Therapeutic Information Complexity Score (TICS). All data was statistically analyzed using SPSS v26. This study comprised 13 consultations of cancer patients, consulting with one female pharmacist, and in 6 consultations the patient was accompanied with a relative. Pharmacist's talk dominance was higher in dyadic consultations (53.49%; U=6.0, p=0.032). The mean number of open questions asked was different from the mean number of closed questions (W=81.0, p=0.013). As to psychosocial to biomedical exchange ratio for the pharmacist to patient talk, the ratio mean value (0.09) was significantly higher for consultations with treatments demanding a higher information-related content (U=2.00, p=0.023). The average patient-centeredness value was 0.31 (SD=0.10) and mean OPTION percentage was 12.69% (SD=5.55%). These results showed that there is still a lack of effective and patient-centered communication in pharmaceutical consultations in oncological area. Professional as well as healthcare organizations should seriously reflect upon the need to continuously prepare hospital pharmacists for the provision of effective and humanistic pharmaceutical consultations.

Keywords: Clinical communication; Patient-centered care; RIAS; OPTION; Hospital pharmacy; Pharmaceutical consultation; Oncology

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Abbreviatures

ACCP - The American College of Clinical Pharmacy

OPTION - Observing Patient Involvement in Shared Decision Making

PCC- Patient-Centered Care

RIAS – Roter Interactions Analysis System

SDM – Shared Decision Making

TICS - Therapeutic Information Complexity Score

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1 Introduction

It is well recognized that hospital pharmacists perform a leading role in health care delivery(1). Hospital pharmacists are a relatively small workforce, mainly in Europe (2). Until 2017, in a total of 53 world countries there were 2824984 pharmacists actively practicing, of which 4% (113349) were hospital pharmacists(1). In Portugal, until 2019 from 15 175 registered pharmacists, 5.4% (820) were specialists working in hospital pharmacy(3).

Hospital pharmacists have several professional duties, being responsible for ensuring that medicines, medical devices, and other pharmaceutical products are effective, safe, and cost-effective, being available on the right time to the right patient. For achieving those goals, the hospital pharmacist is responsible for the medicine circuit at the hospital, including products selection, acquisition, distribution, production, as well as for clinical pharmacy services, patient safety, quality assurance, education and research concerning most therapeutic technologies in use at the site (4).

The role of hospital pharmacists has been changing in the last decades, evolving from an approach focused in manufacturing and dispensing drugs to an approach focused in patient care(5)(6)(7)(8)(9). Until 1950 hospital pharmacists were mainly responsible for guaranteeing quality and standardization of drugs, hardly communicating with patients about their medication and other health-related issues(9)(10). From the 60's, their education improved towards the scientific and technical knowledge needed to provide clinical services that improve health care outcomes(11) i.e. clinical pharmacy(12).

Clinical Pharmacy is defined by American College of Clinical Pharmacy (ACCP) as ''*an area of pharmacy concerned with the science and practice of rational medical use*'' by using knowledge in pharmacology, toxicology, pharmacokinetics, and therapeutics. This discipline aims avoiding drug-related problems by promoting the rational and appropriate use of medicinal products and services, consequently improving healthcare outcomes.

Clinical Pharmacy services are related with better healthcare outcomes (13)(14). These outcomes include improved use of medicines, reduced drug-related problems, and hospitalizations, better clinical outcomes and reduced healthcare expenses (13)(14).

Studies conducted in countries where clinical pharmacy services are well stablished, as Sweden and Australia, showed that these services are cost-effective, because result in less hospital readmissions due to drug-related problems, consequently reducing healthcare costs(13). Drug-related problems are responsible for approximately 5-15% of all hospitalizations (15). Thus, benefits of clinical pharmacy services can be divided in three major outcomes: Economical, Clinical and Humanistic. Economic benefits are reduced avoidable costs and increased cost savings with drugs. On the other hand, clinical benefits are improved prescribing quality, resolution and avoidance of drug-related problems, better medication adequacy and improved therapeutic responses. Lastly, humanistic benefits are improved patients' knowledge of their medicines and higher therapeutic adhesion(14). For other humanistic benefits, such as patient satisfaction and improved quality of life there are still lack of evidence(14)(16). Additionally, evidence shows that the presence of a hospital pharmacist in a chemotherapy preparation unit can prevent an adverse drug event resulting in a positive effect in hospital budget(17).

It is the responsibility of the clinical pharmacist to participate in the treatment decision-making process by evaluating all the aspects of the medication-use process, consulting with the healthcare team and providing direct support to the patient(18)(19). Services provided by a clinical pharmacist include many different tasks, amongst which are the communication of relevant issues to physicians and other health care providers, the education and counseling of patients and caregivers, the monitoring of patient compliance, as well as documenting every care that is provided to each patient(19)(4). Through collecting patient information, review pharmacotherapeutics plans and adverse effects, monitoring therapy adhesion and patient counseling, clinical pharmacists are in the unique position to follow-up patients with chronic diseases, such as cancer patients(10)(20). This usually requires a pharmaceutical consultation with the patient and/or caregivers.

Oncological patients comprise a significant cohort of hospital admissions in general (21). The impact of most cancer treatments in patients' lives has favored the development of ambulatory treatments with oral intake drugs. Due to the usual therapeutic regime complexity of the prescribed treatment for ambulatory patients with cancer, pharmaceutical consultation with oncology patients has been recommended by e.g. the Société Française de Pharmacie Oncologique(20). According to French

specialists, the involvement of pharmacists specialized in oncology may be essential for the management of oral cancer treatment (20). A descriptive study that took place in an oncology unit in a French hospital has shown that the implementation of pharmaceutical consultation to oncology patients contribute to limit drug-related problems by identifying patients unable to self-manage their therapies at home and also drugs and plants interactions. It also showed that pharmacists are essential to provide information to other healthcare professionals(22).

The additional role of pharmacists highlighted a 'new' competence to be addressed: the ability to perform clinical communication(7), i.e. the communication between pharmacists and patients, as well as other healthcare providers. Although recognized for long as a key professional responsibility, it has become a core competence in current pharmacy practice(23)(24). The rational use of medicines in ambulatory at home patients can only be obtained through an effective and appropriate communication(22)(25)(26)(27). Patient consultation is the best way to access patients' needs and concerns and to provide counseling and information(24). An effective communication can contribute to increase adherence to treatment and improve health outcomes for patients(7).

Pharmacists must present skills that enable patients' involvement in the dialogue and decision making(28). This is the scaffolding of patient-centered care, the model of practice that has proven best for achieving the right patient outcomes (29)(30)(31). Patients are treated with compassion, their needs are respected, and care is tailored to patient's conditions(7), priming a relationship of trust. Thus, effective communication skills need to move beyond accuracy and completeness of data exchange. It is mandatory to achieve a professional relationship of trust, characterized by exploring patient's perspective, verbalizing emotional experiences, empathy, shared task-finding and strategy development.

Adequate communication and patient-centeredness are especially important in oncology patients. These patients suffer from great psychological and emotional stress associated with the receiving of bad news and uncertainty regarding their future. Cancer treatments are also a source of distress due to adverse effects or lack of effectiveness. Ineffective communication is known to cause anxiety in cancer patients and dissatisfaction with the care that is provided (31)(32). Thus, from the diagnosis to prognostic, and treatment alternatives, communication must be an efficient way of

exchange information emotionally adjusted: actually, most cancer patients seem to prefer a collaborative approach rather than a professional-centered approach(33).

Pharmacists dealing with oncological patients and treatments need to master the required communications skills. There is some evidence that suggests a gap in pharmacists' communication due to difficulties in shifting from a ''medication-centered'' to a ''patient-centered'' practice(34). These limitations have been studied specially in community pharmacy since the role of hospital pharmacists in face-to-face delivery of healthcare is traditionally less visible. Also, in community pharmacy there is a continuous encouragement of patients to look for pharmacists advise, which does not usually occur in hospital pharmacy. These two factors explain the scarcity of communication studies between pharmacist-patient in hospital settings(35) and particularly pharmacist-patient communication in oncological care (23)(34)(36)(37).

2 Objectives

The main objective of this study is to characterize the hospital pharmacist-patient communication in oncological pharmaceutical consultations. More specifically, the present study was aimed to investigate the level of patient-centeredness and shared-decision making in such clinical interviews, while accounting for treatment complexity and the dyadic or triadic nature of the encounter.

3 Methods

3.1 Study Design

This study followed an observational descriptive cross-sectional design. To investigate the clinical interview accounting for patients' characteristics, all pharmaceutical consultations were performed by a single clinical pharmacist, interviewing oncological patients in a hospital dedicated consultation room.

3.2 Pharmaceutical Consultation

All the pharmaceutical consultations were previously appointed by doctor's advice or pharmacist's initiative. These clinical interviews work in the first medication dispense as counseling sessions for medication management at home or in subsequent interviews to investigate the undergoing treatment outcomes and to suggest improvements of the therapeutic plan to the prescriber and/or patient. All the information collected during the pharmaceutical consultation is registered by the pharmacist in the patient's centralized electronic record. All authorized healthcare professionals may consult the information. As such, the pharmaceutical consultation is formally recognized as any other hospital clinical interview, being a valid and useful component of patient care.

3.3 Sampling and data collection

Consultations were recorded and collected between September 2019 and February 2020 in a central public hospital in Lisbon, Portugal. During this period, all consultations were considered for the study. Each consultation was audiotaped with an audio recorder. Consultations with each patient were only recorded once and after the informed consent of the patients. After collecting the recorded consultations, data was uploaded to one computer and into a specific folder to which only the investigators had access to. Besides the recorded consultations, it was also collected patient's information such as pathologies and therapeutic data, i.e., medicines taken, posology and treatment duration.

3.4 Consultation data coding and analysis

The exchange between the pharmacist and the patient or the accompanied relative was initially coded using the Roter Interaction Analysis System (RIAS)(23). The coding

was accomplished by two independent coders, after proper training. Coding discrepancies were solved by conference agreement using a third coder.

RIAS is a system developed for the analysis of the exchange between patients and physicians that has been widely used(38)(39). The dialogue is divided in utterances, the unit of analysis in RIAS. Utterances are the smallest speech segments that expresses a complete thought, and to which is attributed a code(40). Each utterance produced by the patients and the pharmacist is coded in one of the 41 RIAS categories. Fourteen categories are classified as socio-emotional, and twenty-seven are classified has task-focused(38)(40). The socio-emotional categories are related with building of emotional and social rapport, while the task-focused categories are related with technical skills necessary for problem-solving. The last group include mainly open and closed questions, information giving and patient education and counseling(38)(39)(40). RIAS is considered an appropriate tool for studying the medical dialogue between patients and healthcare providers(39)(40)(23).

The RIAS categories were combined to calculate sums, such as total talk time and pharmacist to patient talk. As well, ratios such as the psychosocial to biomedical exchange ratio for pharmacists. This last ratio is important in oncological consultations knowing sensitive talk should lead the exchange (i.e. ratio >1). Each interview was segmented with RIAS following the medical models of consultation(40). This comprises the five sequential segments i.e. opening, clinical history (diseases, medication, life style), physical examination, counseling and closing(40)(41)(42). All recorded consultations also received the RIAS global affect ratings. In all consultations where a patient was accompanied by a relative, the last would participate actively in the exchange, performing an important role, thus relative's exchange was always considered in the analysis.

Composite indicators were calculated, in this case the RIAS patient-centeredness score. These were calculated based on previously established mathematical formulas (40)(43)(44). Table 1 describes qualitatively these communication variables. Every RIAS variable as well as patients' age and gender, entered a MS Excel file before statistical analysis.

Table 1: RIAS ratios and indicators

Variable	Description
Total talk time* (45)	Total talk time, in minutes, that each participant in the exchange used.
Talk Dominance* (45)	Talk time of each participant divided by total time of the consultation in percentage
Talk Turns* (45)	Number of times that a single speaker produced a continuous segment of uninterrupted utterances (shift on the "floor" between the participants).
Longest Turn*(45)	Longest segment of uninterrupted speech by a single speaker, in minutes
All opened questions(36)	Questions that solicit more than factual restricted information
All closed questions(36)	Questions that produce restricted answers, with few words
Psychosocial to biomedical exchange ratio* (36)	Psychosocial/lifestyle exchange divided by biomedical exchange (for pharmacist and patient)
Patient-centeredness Calculation** (46)	Socioemotional and psychosocial elements of exchange divided by biomedical codes i.e. the sum of 5 composites divided the sum of 3 composites: (Partnership-building talk by pharmacist + Lifestyle/psychosocial information and counseling + Rapport-building emotional + Lifestyle and psychosocial questions by pharmacist and patient + Patient's biomedical questions) / (Biomedical information and counseling by pharmacist and patient + Procedure talk ,orientations + All pharmacist's biomedical questions) Values >1: higher level of patient-centredness

	Values <1: higher pharmacist-centred encounter

*Variable calculated for the pharmacist (when speaking both to the patient and to the accompanying relative), patient and accompanying relative. **Variable calculated for the patient and accompanying relative.

3.5 Pharmaceutical data

The raw data was also examined through a brief content review to searched for key information in pharmacist-patient/relative's dialogues concerning the oncological treatments, in particular drugs' regimens (posology), treatment duration (cycle) and adverse events (safety profile), if any. For instance, the safety profile included side effects and drug interactions. These were obtained via IBM Micromedex and events were confirmed through participants' descriptions (when present).

Oral oncological drugs are frequently associated with complex therapeutic information, such as tailored posology schemes. To address the information and communication-related labour for each treatment, a complexity indicator was deployed, the Therapeutic Information Complexity Score (TICS). TICS was empirically developed by consensus rounds among the research team and 3 hospital pharmacists involved in providing cancer treatment information. It integrates 3 informational aspects of the oral treatment: the drug posology complexity, the number of most frequent side effects and the number of major interactions. The posology complexity would vary from 1 (the least complex e.g. once a day or once a week) to 3 (the most complex e.g. no obvious time regularity or with varying doses). A TICS score was calculated by summing the previous value with the number of side effects and the number of major interactions. The treatments were dichotomised i.e. those with a TICS score lower than 6 were categorized has 0 (lower information demand) and those scoring equal or higher than 6 were categorised as 1 (higher information demand). It was expected more information exchange and associated communication skills for the participants with TICS equal to 1. Patients that presented more than one oral antineoplastic drug were classified with TICS equal to 1. This ad-hoc indicator did not undergo any further validation steps and served only this study purposes, allowing for internal comparisons.

3.6 Patient-centered care

To evaluate patient-centeredness a surrogated measure was used, in this case the level of shared-decision making. It is well documented that patient-centered care (PCC)

encompasses shared-decision making (SDM) (47)(48)(49)(50). Researchers used OPTION (Observing Patient Involvement in Shared Decision Making), as an observational tool developed to study involvement of patients by healthcare providers in the decision-making process. It consists in 12 items that measure SDM by scoring from 0 to 4 healthcare providers' behaviors centered in the patient. The score of each item is summed and is then converted into a percentage(51). Scores above 2 were considered to represent patient-centered behaviors. The tool was applied independently by two researchers, previously trained, reaching a score agreement by a third researcher, when needed. The scores for all interviews entered the same MS Excel file.

3.7 Statistical Analysis

The MS Excel file was imported into an IBM SPSS v26 database. Background and communication variables, as well as the OPTION scores, were statistically analysed. Besides descriptive information (e.g. frequencies, medians, means plus SD), non-parametric statistical tests were used due to the non-normal distribution of most variables in a small sample (e.g. Wilcoxon signed-rank W, Mann-Whitney U, Kruskal-Wallis H). As well, non-parametric bivariate correlations (e.g. Spearman rho) were calculated. These statistical comparisons were calculated for all communication variables comparing patients' dichotomized demographics i.e. patients' and relatives' gender (females vs. males), patients' age (≤79 vs. ≥80 years), dyadic and triadic consultations (pharmacist-patient exchange only vs. exchange with an accompanying relative), and between higher and lower TICS (TICS=1 vs. TICS=0). Only statistically significant differences and associations are presented in Results.

3.8 Ethical authorization

Ethical approval for this study was obtained from the national commission for data protection (Ref. CNPD nº 4653/2018), as well as from the hospital ethics review board (Ref. 30/CES-2018). All data were treated with full confidentiality, complying with the good research practices in social sciences research(52). Data were only available for research team members when necessary to achieve the previously defined objectives.

4 Results

4.1 Background and clinical variables

This study comprised 13 interviews of cancer patients, consulting with one female pharmacist. The professional was 40 years old, with 16 years of clinical pharmacy practice, being on pharmaceutical consultations for the last 2 years. The sampled patients comprised 9 males (69.2%), while the mean age was 77.3 years (SD=7.84). In six of the 13 consultations (46.2%) the patient was accompanied with a relative, mostly female spouses (n=2) and descendants (n=2). All elder patients suffered from at least one malignant tumor, being the most frequent prostate cancer (n=6) followed by rectal cancer (n=3). Three patients suffered from two or more other tumors, while all patients had at least another medical condition. The most frequent conditions were from the cardiovascular system (n= 11). There was no statistical association between patients' gender and having one or more than one tumor (U=12.00, p=0.206).

Concerning the pharmacotherapy, only one patient was not currently under any cancer treatment. From those patients suffering from one tumor only (n=10), 3 were submitted to more than one antineoplastic drug. From the 3 patients suffering from more than one tumor, they were on average submitted to 2 antitumoral drugs. Since all patients presented also concomitant medical conditions, the most frequent drugs were from the cardiovascular system as expected, being also frequent drugs to treat alimentary tract and metabolism conditions, as well as nervous system ones. The minimum number of other drugs besides the antineoplastic was 7 (n=2), with 8 patients receiving 10 or more drugs besides the cancer treatment.

The most frequently used antineoplastic drugs were abiraterone (n=5), capecitabine (n=3), methotrexate (n=2) and cyclophosphamide (n=2). From a total of 11 different antineoplastic drugs being used, most of the drugs (n=8) were for oral administration by the patients on their own, a situation concerning 11 patients i.e. 1 patient was not under any oncological treatment and other patient was not under oral oncological treatment. The remaining antineoplastic drugs were administered via intravenously by a nurse at the day hospital.

The most frequent drug regimens followed by the 11 patients are presented in Table 2. The most frequent posology was one oral dose per day (e.g. abiraterone, which included

2 pills simultaneously), contrasting to the oral administration only at weekends (e.g. methotrexate). The methotrexate and capecitabine showed the most complex posology, respectively, one pill twice a day at weekends only and twice daily with varying dosages along the cycle.

From the safety profile of each oral antineoplastic drug the most frequent side effects (affecting up to 1 in 10 patients) were GI symptoms (e.g. nausea, vomiting, diarrhea) and general physical breakdown (e.g. asthenia, anorexia, etc.), amongst many others. For instance, abiraterone often results in liquid retention and oedema, hypertension, and renal problems (e.g. urinary tract infection).

Regarding other drugs adverse events, potential interactions between antineoplastic drugs and other medications are also presented in Table 2. Only two patients present no significant risk for drug interactions, while most patients (n=10) presented at least one potential drug interaction. Five patients present one major latent interaction with clinical relevance.

Table 2 also presents the TICS scores. From those patients taking oral antineoplastic drugs (n=11), four had a complex treatment (TICS=1), those including methotrexate, cyclophosphamide, and other drugs.

4.2 Communication variables

General characteristics of the exchange in the 13 consultations (e.g. talk dominance, talk turn) are presented in Table 3 and 4, including the consultations (n=6) with triads. Pharmaceutical consultations presented an average duration of 22.74 minutes (SD=7.5 min.). The exchange comprised on average the production of 730.3 utterances in total (SD=277.2) i.e. an average of 32 utterances on total per minute of interaction.

In terms of structure, the missing consultation segments were the physical examination (n=13) and counseling (n=1). For those consultations with all segments, there were repeated ones i.e. the pharmacist went back to a previous segment. This was most frequent with the clinical history (n=7) and the counseling (n=6). The clinical history repeated between three and six times, while the counseling segment repeated up to four times. Nevertheless, six consultations present both sequenced segments just once.

The pharmacist total talk time was on average 11.36 min (SD=3.11) or 51.06% (SD=7.23) talk dominance, while patient and relatives total talk time was 12.35 min

(SD=5.51) or 53.26% (SD=7.48). The total talk turn between the pharmacist and the patient or relative happened 448.15 (SD=180.19) times, including the pharmacist giving the floor to patients or relatives in 195.31 (SD=53.12) occasions. The longest turns were uttered by the pharmacist being the maximum duration of 1.54 min. These longer pharmacist's turns were detected in at least 7 consultations, mainly in the opening and history segments.

The talk dominance from pharmacist and patients' or relatives' values were not statistically different ($p>0.05$) in all consultations. Comparing dyadic and triadic consultations, dyadic consultations showed a significantly higher pharmacist's talk dominance (53.49%; $U=6.0$, $p=0.032$). Comparing across patient ages and gender, as well as with patient relative's gender, no statistical associations were found with consultation time, talk dominance, talk turns and longest turns.

Previous associations were also absent from consultations with higher or lower TICS. However, there was a statistical association between the segment consultation where the longest turn took place and the therapeutic information complexity ($U= 2.00$; $p=0.016$). Consultations with higher TICS (n=4), i.e. when patients had more complex treatments, the longest turns appeared in the opening segment. Those with lower TICS (n=7), the longest turns appeared in the history and counseling segments.

For all 13 consultations the mean number of open questions asked (i.e. medical condition, therapeutic regimen, lifestyle and self-care, psychosocial topics) was 23.46 (SD=22.46), whereas closed questions asked were on average 28.00 (SD=18.71). These values were statistically different ($W=81.0$, $p=0.013$). No statistically significant difference was found between these two types of questions and dyadic or triadic consultations, patient's age groups, patient's and patient relative's gender or TICS.

The results regarding psychosocial to biomedical exchange ratio are described in Table 5. As to psychosocial to biomedical exchange ratio for the pharmacist to patient, the mean value (mean= 0.09) was statistically different between consultations with higher and lower TICS ($U= 2.00$; $p=0.023$) and higher in consultations with TICS=1, thus higher TICS. There was no statistically significant difference between this ratio and dyadic or triadic consultations, as well as with patients' age groups, patients', and relatives' gender. The only other significant difference for this ratio was found for pharmacist to patient-relative exchange according to patient's age group ($H= 3.87$,

p=0.049). The mean value of the psychosocial to biomedical exchange ratio was higher in consultations where patient's age was equal or higher than 80 years.

4.3 Patient-centeredness data

The average PCC value was 0.31 (SD=0.10). No statistically significant differences were found for any of the comparative variables described in Methods. Nevertheless, there was a positive correlation between patient-centeredness calculation and psychosocial to biomedical exchange ratio for patient (rho= 0.945; $p<0.05$).

As to the OPTION analysis, the mean percentage found for all 13 consultations was 12.69% (SD=5.55%). Again, no statistical differences were found between OPTION percentages and all comparing groups. There was a negative correlation, although not strong, between the OPTION results and psychosocial and biomedical exchange ratio for pharmacist to patient (Rho= - 0.569, p= 0.042).

Table 2: Posology, side effects and main interactions of oral antineoplastic drugs within a sample of 13 patients (n)

		Methotrexate	**Capecitabine**	**Cyclophosphamide**	**Abiraterone**	**Others**
Oral Antineoplastic Regimens		Twice daily at weekends (n=2)*	Twice every day (n=3)	Once every day (n=2)*	Once every day (n=5)**	Once every day (n=1) and Twice every day (n=1)*
Most Frequent Side effects	**General physical breakdown (e.g anorexia, asthenia)**	No	Yes	Yes	Yes	Yes
	Gastrointestinal tract (e.g nausea, vomiting, diarrhoea)	Yes	Yes	No	Yes	Yes
	Renal problems (e.g urinary tract infection, aggravation of renal dysfunction)	No	Yes	No	Yes	No

	Cardiovascular problems (e.g cardiotoxicity, hypertension)	No	Yes	No	Yes	Yes
	Immunological problems (e.g myelosuppression, immunosuppression)	Yes	No	Yes	No	Yes
Main Interactions		Three interactions (omeprazole, metamizole)	No interactions.	One interaction (metamizole)	Two interactions (edoxaban)	No interactions.
TICS		1 (n=2)	0 (n=3)	1 (n=2)	0 (n=4)	1 (n=2)

*****Combined therapy; ******One patient does a combined therapy of abiraterone with other

Table 3: Median, Interquartile range, Minimum and Maximum of Talk Time and Talk Dominance of each participant in the exchange for all consultations (N1) and only dyadic consultations (N2).

	N1	Median	IQR	Minimum	Maximum	N2	Median	IQR	Minimum	Maximum
Total time of consultation (min.)	13	21.27*	10.81	12.55	36.53	7	20.48*	7.35	12.55	26.87
Total number of utterances	13	685.00	298.50	463.00	1381.00	7	628.00	187.00	472.00	699
Total time of Pharmacist talk with patient (min.)	13	10.47	4.54	6.42	16.22	7	10.63	5.43	6.42	16.22
Total time of Pharmacist talk with patient relative (min.)	6	2.05	2.14	0.10	5.15	0	-	-	-	-
Pharmacist total talk time (min.)	13	11.34	4.89	6.42	16.22	7	10.63	5.43	6.42	16.22
Total time of Patient talk (min.)	13	10.16	4.54	5.38	18.68	7	10.35	3.02	6.32	11.96
Total time of Patient relative talk (min.)	6	3.45	9.16	0.15	12.37	0	-	-	-	-
Patient and Patient relative total talk time (min.)	13	10.50	5.57	6.32	23.95	7	10.35	3.02	6.32	11.96
Pharmacist talk dominance with patient (%)	13	50.15	15.94	28.72	60.36	7	54.98	12.21	43.91	60.36

Pharmacist talk dominance with patient relative (%)	6	6.91	5.40	0.72	18.33	0	-	-	-	-
Pharmacist total talk dominance (%)	13	52.66	11.10	36.57	60.36	7	54.98	12.21	43.91	60.36
Patient talk dominance (%)	13	47.11	13.79	19.15	61.42	7	50.36	5.87	43.25	61.42
Patient relative talk dominance (%)	6	11.80	28.05	1.08	37.44	0	-	-	-	-
Patient and Patient relative total talk dominance (%)	13	51.27	11.65	43.25	68.79	7	50.36	5.87	43.25	61.42

*W=5.00, p=0.249

Table 4: Median and Interquartile Range of Turn Talks of each participant in the exchange for all consultations (N1) and only dyadic consultations (N2).

	N1	Median	IQR	N2	Median	IQR
Total talk turns	13	399.00	160.50	7	382.00	100.00
Total talk turns of pharmacist to patient	13	191.00	74.00	7	191.00	51.00
Total talk turns of pharmacist to patient relative	6	37.00	56.75	0	-	-
Pharmacist total talk turns	13	191.00	51.50	7	191.00	51.00
Total talk turns of patient	13	191.00	63.00	7	191.00	51.00
Total talk turns of patient relative	6	93.00	142.50	0	-	-
Patient and Patient relative total talk turns	13	185.00	79.50	7	191.00	51.00

Table 5: Median and Interquartile Range of psychosocial to biomedical exchange ratio for each participant in the exchange for all consultations (N=13).

	N	Median	IQR
Psychosocial to biomedical exchange ratio for pharmacist to patient	13	0.07	0.11
Psychosocial to biomedical exchange ratio for pharmacist to patient relative	6	0.02	0.57
Psychosocial to biomedical exchange ratio for patient	13	0.22	0.15
Psychosocial to biomedical exchange ratio for patient relative	6	0.27	0.57

5 Discussion

This study aimed to provide a first description of the sociolinguistics behind the exchange between one hospital pharmacist and her oncological patients, whose cancer medication is subject to therapeutic monitoring. Oral ambulatory cancer medications pose special challenges to healthcare professionals, who are expected to empower patients towards treatment self-management (53). Although oncological patients usually comply with treatments and show awareness of therapy outcomes (54), cancer treatments are known to be a source of distress associated with the uncertainty regarding adverse events and effectiveness in tumor remission. Hence, communication features and related competencies gain particular relevance in these consultations, recognizing that ineffective communication is known to cause anxiety in cancer patients and dissatisfaction with the care provided (31)(32). Additionally, most cancer patients seem to prefer a collaborative approach (33), highlighting the importance of patient-centered communication.

5.1 Communication traits in oncological pharmaceutical consultations

In this study, almost half of the recorded consultations were triads. An accompanying relative was somewhat expected, especially in elderly oncological patients(55). In other studies has been related that oncological patient prefer to be accompanied by a relative to the consultations (56)(57). Family members have an important role in consultations because give relevant information about patient's socio-cultural, psychosocial and clinical background and collaborate in the decision-making process(58)(59). Sometimes information given by a family member is more reliable than information provided by the patient(57). On the other hand, in oncological patients the presence of a relative gives the emotional support necessary to overcome potential bad news(57).

On the other hand, pharmaceutical consultations were held with a patient that had already concluded the antitumoral cycles. However, due to the high number of other concomitant drugs, the patient could benefit from medication review. This indicates the pharmaceutical consultation is being recognized as other hospital consultations, helpful in optimizing patient care (60)(61).

Pharmaceutical consultations in community pharmacy are expected to last approximately 15 min (62)(63). On the other hand, consultations in hospital settings have a duration ranging from 10 to 20 minutes(64). Studies show that pharmaceutical consultation in hospital setting last in average 7 min, ranging from 3 to 30 min (35). Although, there is a difference in consultations duration depending on the aim of the consultation. Consultations where only outcomes are measured have a shorter duration than those where therapeutic features are discussed(63)(65). Some studies showed that patients prefer longer consultation, although in longer consultations are prescribed less medicines and are given more counsels about lifestyle habits to promote a healthier life(64). Thus, the average time of these consultations (22.74 minutes) is higher than the standard hospital consultations and community pharmacy consultations. Although these may be justified by the fact that oncological patients have more complex treatments and need more psychosocial support. This is supported by the fact that medical oncological consultations have an average duration of 60 min, higher than consultation of other medical condition (66). Also, total time of consultation was higher in triadic consultations, that could be explained by the participation of the family member (58)(59). On the other hand, total time of pharmacist talk with patient was higher in dyadic consultations. This may be explained by the fact that in dyadic consultations, pharmacist only needs to interact with the patient, without needing to divide attention with a third element(67). Nevertheless, from an average of 730 utterances and 448 talk turns, the pharmacist gave the floor only 195 times, showing there are opportunities to increase communication interactivity.

One important communication feature needed to increase clarity in the exchange is to pace speakers' interventions during the interchange. Thus, while listening to the consultations often both professional and patient and/or relative were not respecting others floor of speech. Although culturally understandable(68), this overlapping may disrupt the exchange clarity and efficiency(35)(69). Normally, in a conversation is expected to exist the right to speak and receive attention, where only one-part talks and the other part is being oriented in what is being said and is expected to be the next speaker(35). The fact that there was not only one speaker confuses the patient about the purpose of the consultation because the patient perceives it as a mundane conversation rather than an institutional conversation. Also, and because there are still doubts about the extended-role of hospital pharmacists has face to face healthcare providers(35), the

patient may not perceive the pharmaceutical consultation as a consultation with a shared specific goal (i.e therapeutic review, monitoring adhesion, monitoring drug interactions) to improve patient's health outcomes. Nevertheless, there was no obvious talk dominance in these consultations as observed in other studies with pharmaceutical consultations(63)(69), which is opposite to what has been described in medical consultation where physician talk dominance is normally higher(55).

However, a lower pharmacist talk dominance was observed in triadic consultations. Triadic consultations have a more complex nature due to the three-way exchange and are more difficult to conduct (67), because healthcare provider has to respond to expectations of both patient and family member and involve both in the dialogue. Interactions with three voices may be seen as social exchanges that can create more confrontation and talk dominance imbalance(55). On the other hand, family members normally participate actively in the dialogue(57), thus patient-relative talk dominance is expected to be significant. Besides evidence shows that the presence of a relative improves patient engagement and interest in collaborate with the professional (55), thus in triadic consultation patient talk dominance is expected to be high. Also, as the conversation can be directed to the pharmacist in two ways less opportunities are created for the pharmacist's dialogue.

The clarity of the consultation goals and steps are defended by most medical models, where the consultation structure and organization are normally overt (33)(42). Pharmaceutical consultations should present an equivalent segmentation, although missing the physical examination due to their nondiagnostic nature. The one interview missing the counseling segment was the shortest consultation, which was oriented to only collect medication information (history). Repetition of the history and counseling segments was found suggesting cycles of shortened patient data collection and associated advice, which was also described for medical consultations (70). Nevertheless, 6 consultations present both sequenced segments just once, highlighting a purposeful structure that supports the relevance of this service (63).

Patient data collection, predominant at the history segment, involved the open and closed-ended questioning, with a predominance of the later. Using open questions, especially in the beginning of consultations(7), is considered effective communication (71), because explores the problem more deeply and gathers information more effectively(72). On the other hand, studies have confirmed that patient activation is

related with the type of questions used, because open questions enable to explore more efficiently patient's doubts and worries(72), thus facilitates relationship building and is considered patient-centered care(7)(73). Although, closed questions contribute to more frequent change of speech floor, hence result in a more interactive exchange(45). In other studies has been referred that in oncological consultations opened questions are predominant(36). So in this study, the predominant use of closed question may mean that the pharmacist was mainly confirming assumptions(72) and looking for more specific information(7). This might impinge on developing rapport and partnership building.

The longest turns where uttered by the pharmacist and this may be related to the use of the speech floor to take advantage of other parties' silence. However, these longest turns occurred mainly in the opening and history segments. Probably because these were first consultations the pharmacist wanted to collect the maximum information (clinical and social) from the patient, and by doing so produced longer turns. These findings are contrary to other studies, where giving a short introduction and asking questions were the lowest contribution to pharmacist-patient interaction(74). On the other hand, longer turns do not necessarily mean lower dialogue interactivity or that a feedback is not produced. There are two types of communication: verbal and non-verbal(75). Non-verbal communication complements or substitutes verbal language and refers to facial expressions, body language, voice tone and posture(75). Non-verbal interactions are not considered when coding in RIAS, except voice tone(40). Thus, in longer turns might have exist non-verbal feedback that was not analyzed. Non-verbal communication is important in the patient-centered care because is related with emotional aspects that are essential for the relationship building, while verbal communication related more with technical knowledge and competency(76). Nevertheless, the longest turns should emerge from the patient after pharmacist's open-ended questions in the history segment. Otherwise, the longest turns could have been produced by the pharmacist in the counseling segment.

More complex treatments are expected to have a higher information burden, but surprisingly the longest turns appeared in the opening segment for patients with higher TICS, while patient with lower TICS the longest turns appeared in the history and counseling segment. In the beginning of a consultation the initial greetings are made and is established the initial rapport between patient and healthcare professional, and

the reason for the consultations is presented(77). In the history segment information is collected by questioning and listening and the patient's perspective is considered (77), and in the counseling segment advices about medical conditions, treatments and lifestyle/psychosocial problems are given(63). Thus, one possible explanation is that the pharmacist knew the therapeutic information complexity on advance, from patient's clinical process, and gave a more detailed explanation of what the consultation would be without giving an opportunity to be interrupt(78). This also might influence patients to regard the consultation as valuable, thus respecting the speech floor. Also, in the other segments the turns where probably shorter, meaning that the conversation floor switched more frequently in those segments. More frequent changes in speech floor is related with more opportunities for patient to talk, therefore higher patient's contribution to the dialogue(78). Especially in oncological patients with more complex treatments is important to create occasions where the patient can talk(78) in order to understand medication adherence and self-management at home(26).

5.2 Humanistic traits in oncological pharmaceutical consultations

The degree of humanity and compassion in clinical interviews can be approach through different angles. One is to look at the psychosocial to biomedical exchange ratio, which enables to evaluate the main content and orientation of the consultation. In the present study, the mean value for this ratio was lower than in other studies (79). This indicates the dialogue was mainly based in biomedical and therapeutic topics rather than psychosocial and lifestyle talk(36). Evidence shows that this is common in consultations, especially in oncological consultations(36). This is not ideal, especially in diseases where psychological distress and anxiety are common(80).

Psychosocial management is usually part of oncological clinical interventions by multidisciplinary teams (80)(81). In addition, pharmacists must address complex treatments. This might push the conversation focus towards therapeutic and biomedical matters, responding in particular to medication adverse effects and drug interactions. Although, more complex treatment are known to be associated with cancer-related distress (80)(82). Thus, a psychosocial to biomedical ratio higher in consultation where patient had more complex treatment was expected. Cancer-related distress is described has an emotional experience that interferes with patient activation and engagement(83). When patient distress is recognized patient's satisfaction, decision-making and adherence to treatment are improved(83). In the present study, it was not investigated

the extent to which these concerns were tackled by the pharmacist. Nevertheless, the psychosocial to biomedical exchange ratio for the pharmacist to relative was higher in consultations with patients over 80 years. This is important for reducing cancer-related stress knowing older cancer patients suffer from psychosocial problems more frequently than younger patients(84). On the other hand, pharmacist psychosocial ratios were lower than patient and patient-relative psychosocial ratios, meaning that patients and patient-relatives used more psychosocial exchange than pharmacist. This was expected, because healthcare providers tend to use more biomedical and scientific terms than patients(34)(7).

Humanistic traits such as patient-centeredness are related with psychosocial talk, because patient-centered care considers not only biomedical and therapeutic characteristics but also psychosocial aspects, such as patient needs, preferences, beliefs and values(7)(85). Thus, the fact that a richer psychosocial talk leads to a more patient-centered communication(7)(85), a positive correlation between patient-centeredness calculation and psychosocial to biomedical exchange ratio for patient was expected.

In these consultations PCC was lower than reference value of 1(46). In other study, patient-centeredness was also measured in pharmaceutical consultations with simulated patients and the mean value was 0.56(79), that is higher than the mean value (0.31) of patient-centeredness in these consultations. This means that patient-centeredness is still poor in oncological pharmaceutical consultations. This can result from not using an effective communication. Most patient's complaints about healthcare professionals are about ineffective communication and not lack of clinical knowledge and competence(33). On the other hand poor communication can limit patients' adherence to treatment and can jeopardize pharmacist-patient relationship(30). Effective communication is described as communications skills in creating a relationship of trust with the patient, considering patient's perspective and emotional experiences, show empathy, and involve patient in the decision-making process (30)(76).

Therefore, the SDM is related with patient-centeredness(47)(48)(49)(50). SDM can be about therapeutic treatment, lifestyle action or any other decision related with patient's health, even not taking any action. Evidence shows that when the patient is involved in the decision better clinical outcomes, better patient satisfaction, cooperation and treatment's understanding are expected (86)(29)(30). SDM is associated with patient empowerment, a process in which patients understand their role and are encouraged to

participate and self-manage their healthcare problems by knowledge and skills given by their healthcare providers(73). When patients are involved and understand their plan of care, adherence is facilitated because they are more able to self-manage their therapies at home (24). Nevertheless, in a systematic review comprising studies that measured SDM in several types of medical consultations using OPTION, the average score was 23% (SD=14), and in a consultation with a patient with breast cancer the score was higher than 50 (87). Thus, OPTION results from these consultations are lower than those in other studies. This may mean than in pharmaceutical consultations patients are not being involved in the decisions.

Therefore pharmacists should allow patient participation in their care by using patient-centered communication(7)(85). The fundamental concepts of patient-centered communication include obtaining and understanding patient perspectives, psychosocial and cultural contexts (e.g., concerns, expectations, feelings) and achieve a shared understanding of treatments accordingly patients' believes(85). Although, evidence shows that there are some barriers to this type of communication in pharmaceutical consultations that were also detected in this study. Sometimes is difficult for the patient to articulate their concerns without being interrupted by the pharmacist, also treatment choices consider only clinical aspects rather than patients' values and preferences. On the other hand, pharmacists rarely incorporate a holistic understanding of patient's psychosocial and cultural characteristics in the evaluation of indication, effectiveness, safety, and adherence of medications(85). Therefore, the pharmacist must develop patient-centered communication skills, such as express empathy, listen actively, and make eye contact to create a relationship of trust. On the other hand, to gather information the pharmacist should ask opened questions, allow patient to complete ideas and responses, clarify and summarize information. Also, to give information the pharmacist should use a language that is understandable by the patient, encourage questions and check for understanding. Then again, to achieve a shared decision-making, patient preferences should be explored to identify barriers to treatment and negotiate agreements. Lastly, to guarantee treatment success the treatment plan should be summarized and follow up discussed(30)(72)(85).

5.3 Practice Implications

Pharmacists' clinical communication skills need to be developed in the context of formal consultations, aiming to optimize the interview process and achieve the best outcomes in ambulatory treatments. Also, communication skills training needs to incorporate principles and practices of patience-centered care and share-decision making linked to medication usage. Lastly, recognizing the work pressures and the preference for vocational education comprising medication related knowledge, onsite evaluation with video-feedback is recommended, while policy measures are needed to strengthen behavioral training.

5.4 Study limitations

The present study is an exploratory study with few consultations in a hospital setting, which makes not possible to extrapolate the results for other pharmaceutical contexts. Additionally, as the analysis was based on audio-recordings, non-verbal indicators were not explored, which might limit the contextual depth of the gathered data. Also, one patient was not under antitumoral medication, and another patient was not taking oral antitumoral medication, thus adherence to oral oncological treatment was not applicable in these two cases. On the other hand, there was no validation of TICS, although it was developed with experts' contributions and based on factual and objective information. Lastly, the correlation between PCC and SDM was not significant within this sample (rho=-0.03, p=0.934) which may restrict the linkage assumption between these two constructs.

6 Conclusion

Although clinical pharmacy benefits have been reported, hospital pharmacist's communication characteristics with patients and humanistic traits have received little previous attention from researchers. The present results show that effective and patient-centered communication in oncological pharmaceutical consultations presents constraints, even if not critical in terms of clinical communication elements. Nevertheless, elements need to be considered and developed as other competences, such as an overt consultation organization and flow, while building a clearer relationship with the patient and the accompanying relative. Pharmacists should listen actively, respect patients' floor, express empathy, consider patients' values and beliefs, use further open-ended questions, encouraging patient participation, clarify and summarize information. Thus, hospital pharmacy needs continuous education and vocational training besides drugs and treatments. Professional as well as healthcare organizations should seriously reflect upon the need to prepare hospital and clinical pharmacists for the provision of effective and humanistic pharmaceutical consultations.

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Annexes

Annex 1 - Submission to Patient Education and Counseling