Article

Journal of Mixed Methods Research
1–26

DOI: 10.1177/1558689818792793
journals.sagepub.com/home/mmr
SAGE

Crossover Mixed Analysis in a Convergent Mixed Methods Design Used to Investigate Clinical Dialogues About Cancer Treatment in the Japanese Context

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Abstract

The convergent mixed methods design is a common mixed methods research strategy; however, a challenge arises when data are collected concurrently but not analyzed completely independently due to overlapping research aims or certain styles of reasoning. The aims of this study were to (1) implement a crossover-tracks analysis in a convergent design wherein qualitative and quantitative strands were intertwined and informed each other and (2) examine a working hypothesis about the relationship between temporal change in clinical dialogues to examine the strength of patients' motivation to participate in a clinical consultation. Using hypothetico-deductive method, the dynamic analytical approach shifted between inductive and deductive approaches. The qualitative and quantitative results were merged, and a joint-display depicted the relation for the final interpretation.

Keywords

case-oriented analysis, *ki-shou-ten-ketsu*, informed consent, cancer patients, shared decision making

Many mixed methods designs have been developed for mixed methods research (Creswell, 2014, 2015; Creswell & Plano Clark, 2011; Greene, 2008; Hesse-Biber & Johnson, 2015; Leech & Onwuegbuzie, 2009; Morse, 1991; Tashakkori & Teddlie, 1998, 2010; Teddlie & Tashakkori, 2006, 2009). In a convergent design (Creswell, 2015; Creswell & Plano Clark, 2011), also known as a concurrent parallel design (Tashakkori & Teddlie, 1998, 2010; Teddlie

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& Tashakkori, 2009), researchers typically collect qualitative and quantitative data concurrently, analyze the data types independently, and compare the results. However, a variation occurs when data are collected concurrently but not analyzed completely independently due to overlapping research aims or certain styles of reasoning (Johnson & Gray, 2010).

Parallel-Tracks Analysis and Crossover-Tracks Analysis

Teddlie and Tashakkori (2009, pp. 268-269 in citing Datta, 2001, p. 34) refer to two types of mixed methods analysis for this design: *parallel-tracks analysis*, and *crossover-tracks analysis*. In parallel-tracks analysis, ''the analyses are conducted independently, according to the strands of quality and excellence for each method . . . and the findings are brought together after each strand has been taken to the point of reaching conclusions'' (Teddlie & Tashakkori, 2009, pp. 268-269 in reference to Datta, 2001, p. 34). In a crossover-tracks analysis, during the analysis process ''findings from the various methodological strands intertwine and inform each other throughout the study'' (Teddlie & Tashakkori, 2009, p. 269 in reference to Datta, 2001, p. 34). Greene, Benjamin, and Goodyear (2001, p. 31) place parallel-tracks analysis within a pragmatic and crossover-tracks analysis within a dialectic framework, but assert that ultimately ''mixed-method practice is much more complex and dynamic than theoretical constructs can capture.''Onwuegbuzie, Slate, Leech, and Collins (2007, p. 12) describe the *mixed analysis* procedure as ''an analysis technique that is more associated with one traditional paradigm to analyze data that originally represented the type of data collected that are more often associated with the other traditional paradigm.'' Several researchers previously have published examples of crossover-tracks analysis (Datta, 2001; Greene, 2007, pp. 156-157; 2008; Li, Marquart, & Zercher 2000; Teddlie & Tashakkori, 2009, p. 269). However, examples illustrating interactive data analysis focusing on mixed hypothetico-deducto reasoning styles are lacking.

A study examining Japanese patients' practices of informed consent for chemotherapy provides an example of research that used a crossover-tracks analysis incorporating mixed hypothetico-deducto reasoning styles. Background information about the informed consent changes occurring in Japan, and the rationale for conducting the study provides context for understanding the crossover-tracks analysis procedure we will illustrate.

Informed Consent

Informed consent aims to protect patients legally and ethically by honoring their autonomy and to ensure the ethical practice of medical research and clinical treatment (Beauchamp & Childress, 1996; Council for International Organizations of Medical Sciences, 2016; Emanuel, Wendler, & Grady, 2008; Hall, Prochazka, & Fink, 2012; Office for Protection from Research Risks, 1979). Despite the conceptual intent, the term has different meanings for different people, especially in clinical settings (Bernard, 2005). For example, in Japan as in many countries, informed consent has become a part of everyday practice but the meaning is interpreted within the country's social and cultural contexts (Elwyn, Fetters, Gorenflo, & Tsuda, 1998; Fetters, 2015; Long & Long, 1982; Ohtaki, Ohtaki, & Fetters, 2003; Saldov, Kakai, McLaughlin, & Thomas, 1998; Specker, 2017).

Informed Consent in Japan

While the concept of informed consent was introduced into Japan during the 1980s, it did not catch on straight away (Fukushima, 1989; Hoshino, 1997). At this time, Japanese patients generally did not question the wisdom of their doctors (Hadfield, 1993) who would often avoid

informing patients of their diseases, especially cancer (Elwyn et al., 1998; Kai et al., 1993; Morioka, 1991). Such was the case even for Emperor Hirohito who died from duodenal cancer in 1989 (Takahashi, 1989). In 1993, an advisory panel to the Health and Welfare Minister began discussing what manifestation informed consent should take in Japan (Yanagida, 1996). According to Leflar (1996), the panel encouraged wide diffusion of informed consent in medical practice while emphasizing to physicians that it should be valued as a therapeutic aid and not feared as a legal hazard. However, the panel rejected codification of informed consent rights, in favor of boosting efforts to educate medical professionals on the concept (Leflar, 1996; Yanagida, 1996). The Japanese conception of informed consent has been discussed most extensively with regard to disclosure of the cancer diagnosis or so-called ''truth telling,'' and to the physician–patient relationship (Feldman, 2000; Leflar, 1996). While debate occurred about the extent cancer disclosure was occurring as an informed consent practice in Japan, the mere act of a physician's explaining prospective treatment and requiring the patient's agreement to move forward would not necessarily constitute acceptable informed consent by most international standards (Fetters, 2015) This illustrates a Japanese variation, namely disclosure of the diagnosis, as one interpretation of informed consent.

In the 2000s, with advancements in medicine, the Japanese government began promoting transition to outpatient chemotherapy (Ministry of Health, Labour and Welfare [MHLW], 2007) and sought to improve the informed consent process and expectations for routine use (MHLW, 2012). Written in the publication *Gankanjya wo fukumeta kokumin nado no doryoku* or Effort of the people including cancer patients (author's translation) (MHLW, 2012, pp. 34-35), a tenet described as *infomudo konsento eno junbisei* or ''readiness for consent'' (author's translation), this development promoted the expectation for patients to take a greater interest in their treatment prior to informed consent consultations. The driving force is the intent of ensuring that cancer patients commence outpatient chemotherapy safely, reflecting requirements under the *Cancer Control Act*. Furthermore, the Act set the expectation for physicians to provide patients with full explanations and to build trusting relations founded on patients' understanding of their underlying illness and treatment options. In a literature review, Fujimori, Uchitomi, and colleagues identify studies examining physicians' skill at sharing bad news about cancer treatment (Fujimori et al., 2007; Fujimori et al., 2014; Fujimori & Uchitomi, 2009). Unfortunately, little is known about the relationship between patient proactive interest in treatment prior to starting consent consultations and their proactive attitudes after building a trusting relationship with their physician.

Patient Motivation and Interest

We developed previously a scale to measure patients' proactive interest in treatment prior to consent consultations and their proactive attitudes after building a trusting relationship with their physician called the Achievement Motivation Index for Medical Treatment (AMI-MeT; Hatta et al., 2016). The AMI-MeT, or in the following just the ''Motivation for Treatment Index,'' based on the theory of planned behavior (Ajzen, 1991). This index measures patients' self-derived proactive interest in participating in decisions about their treatment. To examine the relation between proactive interest in participating in informed consent dialogue and temporal changes in that dialogue, we launched the research project: Mixed methods Observational Research for Informed Consent [MORE-IC] (MORE-IC, 2009). The study objectives were to (1) assess the strength of patients' motivation in choosing their treatment by using Motivation for Treatment Index (MTI) and (2) illustrate how doctor–patient dialogues differed between patients with high and low treatment choice motivation. Using this study, our methodological objective is to illustrate a highly interactive analysis of convergent mixed methods data using inductive and deductive approaches.

Method

Working Hypothesis, Hypothetico-Deductive Method, and Mixed Methods Design

In this study, we explore the relationship between patients' interest in participating in decisions about their treatment and the temporal structure of dialogues within the informed consent consultation process. As mentioned above, prior to around 1990 Japanese patients entrusted decision making to their medical doctors (Hadfield, 1993), since that time interaction around decision making in the Japanese physician–patient relationship has gradually shifted from this *omakase model* to a *participatory model* (Slingsby, 2004). Patients following the omakase (entrusting) model are described as reluctant to engage in or lack the initiative to participate actively in decision making. Rather, they entrust their decision making to medical professionals. In contrast, patients following the participatory model actively participate in decision making with more dialogue with their physician (Slingsby, 2004). Despite the articulation of these two models of decision making, the relationship between patients' self-derived proactive interest in participating in decisions about their treatment and the temporal structure of their dialogues with physicians remain unclear. In this research, we hypothesized that informed consent dialogues of patients with higher motivation and interest in treatment would reflect greater interest in participating in the dialogues.

To test this working hypothesis, we adopted a hypothetico-deductive method to use in the research, which according to Schwandt (2014) should ideally involve five steps:

> Step 1) Theory first provides definitions and assumptions about human behavior; Step 2) predictions (hypotheses) about behavior are then logically deduced from theory; Step 3) predictions are then tested through empirical observation; Step 4) based on the results of tests of the hypotheses, the inquirer then concludes that the theory is either consistent or inconsistent with the facts (i.e., it explains or does not explain the behavior); and Step 5) if experimental results and theory are consistent, no further work is needed; however, if they are inconsistent, then the theory must either be discarded in favor of a better theory or modified to accommodate the newly acquired facts. (pp. 148-149)

In relation to the first two steps, one must first have a theory to test, an aspect the hypothetico-deductive method tends to neglect (Teddlie & Johnson, 2009). Given that our assumptions could be questioned as fully meeting the criterion of rigor, we framed our hypothesis as a *working* hypothesis. For empirical testing with a convergent design as mentioned in the Step 3 above, we employed participant observation. This allowed collection of qualitative and quantitative data concurrently, and the opportunity to articulate the working hypothesis through inductive analysis (Schwandt, 2014; Strauss, 1987). It allowed us to identify the participants for qualitative analysis (*connecting*; Fetters, Curry, & Creswell, 2013). This then allowed us to explore the temporal framework of dialogue through inductive and deductive thinking (Strauss & Corbin, 1990). We could then *merge* qualitative and quantitative data (Creswell, 2015; Fetters et al., 2013) and finally to depict both types of data in a side-by-side joint display (Creswell, 2015; Fetters et al., 2013; Guetterman, Fetters, & Creswell, 2015). As for the fourth step, we provided an interpretation to support the working hypothesis. Finally, for the fifth step, we discussed limitations of empirical study and a caveat regarding the mixed methods design (Figure 1).

Participants, Participant Observation, and Data Collection

Clinical Setting, Sampling, and Participants. We conducted the study in a university hospital in Kyoto whose outpatient oncology unit had begun to offer outpatient chemotherapy at the request

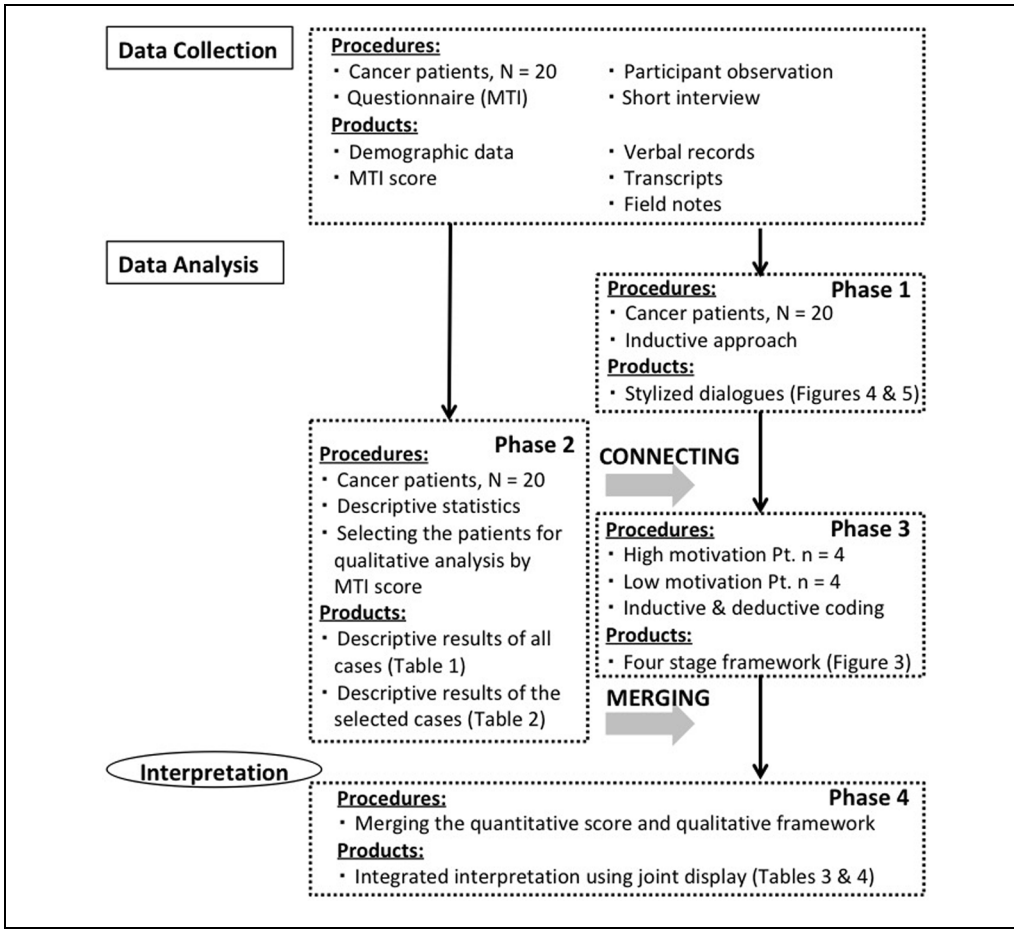

Figure 1. Procedural diagram of the convergent study design.
Note. MTI = Motivation for Treatment Index. IC = informed consent.

of other hospitals and departments. We recruited from among oncologists with over 10 years of clinical experience who were routinely involved in informed consent consultations at the unit: one lung cancer specialist and one breast cancer specialist.

At the time of the study, the lung cancer patients in the unit had already received an explanation about their cancer and about chemotherapy, given consent to start chemotherapy, and received inpatient treatment. When they were transferred from inpatient to outpatient treatment, they again had to give their consent. In contrast, the breast cancer patients had been referred by breast surgeons to receive intensive preoperative chemotherapy, but had not yet received chemotherapy and had received only limited information about their treatment.

Despite these differences, based on the observation goals and the limited accessibility of clinical settings, we planned to collect both qualitative and quantitative data through purposive sampling. We used published recommendations for the sample size (Teddlie & Yu, 2007), usually 30 cases or less. A feasible sample size for us was 10 patients from each group, a total of 20 patients.

The participants were selected by approaching consecutively lung cancer patients and breast cancer patients who met eligibility criteria for the study and visited the outpatient oncology unit

Table 1. The Characteristics of the Patients and the Informed Consent Consultation.

	n
Patients	
Sex	
Male	7
Female	13
Age (years), mean ± *SD*	60 ± 11
Cancer	
Breast	10
Lung	10
Cancer stage	
I	3
II	4
III	5
IV	8
Previous use of anticancer agents	
Use	11
Nonuse	9
MTI, mean + *SD*	60 ± 8
IC consultation	
Time (minutes), mean + *SD*	58 ± 15
Family presence	
Family presence	13
Patient only	7

Note. MTI = Motivation for Treatment Index. IC = informed consent.

of the hospital from January to July 2009. Patients were eligible for the study if they (1) had been diagnosed with cancer and had been informed of their cancer, (2) were meeting the oncologist for the first time, and (3) were deemed by the oncologist to be at low risk for psychological distress from study participation. In all, 25 patients were invited to participate; 20 gave consent for both the questionnaire and observation, 2 agreed only to answer the questionnaire, and 3 did not give consent at all. Thus, 20 of 25 patients provided complete data that we analyzed for the study (Table 1). The study protocol was approved by the institutional review board at Kyoto University Graduate School of Medicine (E-570) and was registered in Japan's UMIN Clinical Trials Registry (MORE-IC, 2009).

Qualitative and Quantitative Data Collection. We collected qualitative and quantitative data simultaneously during participant observation (Flick, 2009) from the stance of an observer-as-participant (Gold, 1958). The lead researcher (the first author) contacted potential study participants in the unit's waiting area, explained the study aims, and obtained written consent. A copy of the consent form is included as Appendix A (available in the online version of the article). Participants completed a questionnaire sheet covering age, sex, experience receiving chemotherapy, and motivation and interest in treatment. The lead researcher made audio-recordings of the informed consent consultations using a digital voice recorder and took notes describing the situation (e.g., seat configuration, demeanor of oncologist and patient, and any feeling of tension). Immediately after each consultation, the oncologist and patient were separately asked to reflect about their conversation (within a few minutes of the encounter). Within several days of each observation, the lead researcher transcribed all audio-recordings. Then, the research team developed a quantitative database including the patients' age, sex, experience of

chemotherapy, type of cancer, cancer grade, interest and motivation in treatment as measured by MTI, presence of family during the informed consent consultations, and the length of informed consent consultation (minutes). The research team also developed a qualitative database with consultation voice recordings, consultation transcripts, short postinterviews, and field notes.

Data Analysis

Crossover Analysis and Integration in the Mixed Methods Design. This concurrent data collection allowed crossover-tracks analysis and several types of integration in the mixed methods design (Figure 1). The first crossover (deductive to both inductive and deductive) occurred between the Phase 2-QUAN and Phase 3-QUAL. It allowed us to identify the participants for qualitative analysis (connecting; Fetters et al., 2013). The second crossover occurred in analytical strategies in qualitative strands (inductive to both inductive and deductive) when switching from the Phase 1-QUAL to the Phase 3-QUAL (Figure 2). A third crossover was also analysis switch (both inductive and deductive to deductive) from Phase 3-QUAL to Phase 4-QUAL (Figure 2). Each earlier phase informed the analytical strategy for the subsequent phase. The fourth crossover occurred between Phase 3-QUAN and Phase 4-QUAL, when the qualitative results were integrated with the QUAN results in order to test the hypothesis. To draw meta-inferences from the mixed findings, we merged the qualitative and quantitative results using a joint display (Creswell, 2015; Fetters et al., 2013).

Analytical Shift from Inductive to Deductive Approach. To examine patients' interest in participating in treatment decisions and to identify temporal changes in the informed consent dialogue, we used *case-oriented analysis*, which is best suited to identifying patterns common to one or a few cases (Onwuegbuzie, Johnson, & Collins, 2009; Onwuegbuzie, Slate, Leech, & Collins, 2009). In the process, we shifted from an inductive approach (Schwandt, 2014; Strauss, 1987; Strauss & Corbin, 1990) to a deductive approach (Strauss & Corbin, 1990) to prove the working hypothesis under the hypothetico-deductive method (Figure 2).

Phase 1-QUAL (Inductive): Participant Observation Elucidating Stylized Dialogue. To support case-oriented analysis and ensure dependability of participant observation, the first author briefed the second author on the informed consent consultations after each of 20 cases of observation. The first author (a researcher on bioethics and a nonclinical practitioner) conducted all participant observations; the second author (KN) was a clinical psychologist engaged in the palliative care unit in the university hospital, who was also familiar with the functioning of the outpatient chemotherapy unit.

Through peer-debriefing (Schwandt, 2014), the two analysts inductively divided the consultation content into two categories (Strauss, 1987): *stylized* dialogues, wherein oncologists informed their patients of task-focused elements of medical treatment, and *impromptu* dialogues, wherein oncologists responded to the personal interests of the patient. These analyses were undertaken before sampling based on MTI. As we transitioned to Phase 2, the analytic strategy was inductive.

Phase 2-QUAN (Deductive): Quantitative Analysis and Case Selection. After completing observation of all 20 patients, we calculated descriptive statistics for the demographic variables to describe the participants' characteristics and statistically compared MTI scores, informed consent consultation time, and disease stage between groups using SPSS Statistics 22.0 (IBM Corp., Armonk, NY).

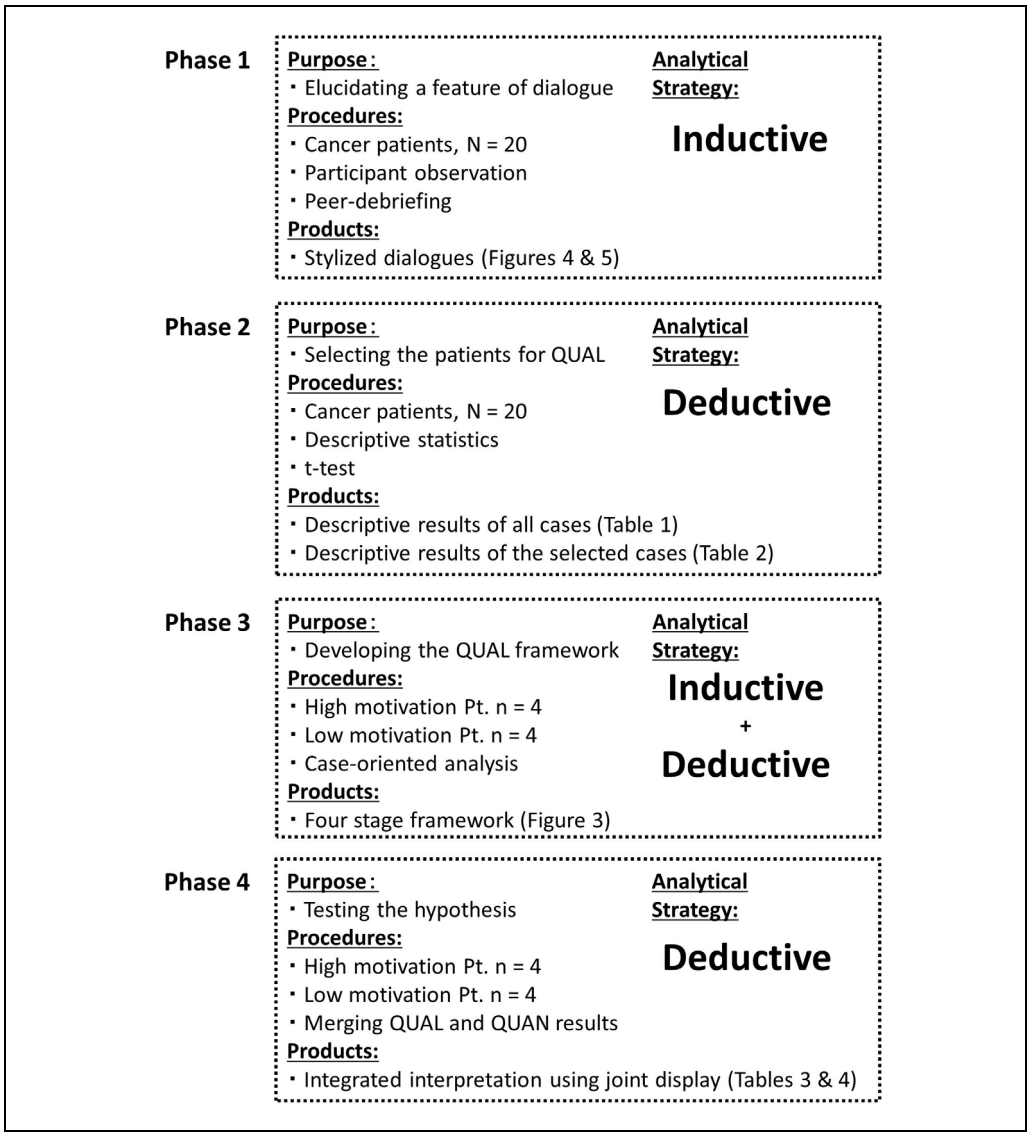

Figure 2. Analytical shifting between inductive and deductive approaches during the crossover analysis.

The MTI asks responders about their ‘‘personal interests and values that could exert a potent influence on medical decision making and that would be influenced by social norms or expectations’’ (Hatta et al., 2016). On the concept of motivation, a previous study noted,

> Physician–patient communication, and the intention underlying patients’ communication about their medical treatment, relates to several factors, such as the social values of the hospital, expectations for medical treatment, preferences for communication style, and so on. Notably, these factors can be interpreted according to the theory of planned behavior (Ajzen, 1991), as they correspond to the concepts of attitude toward the behavior, subjective norms, and perceived behavior control, which all influence intention. (Hatta et al., 2016)

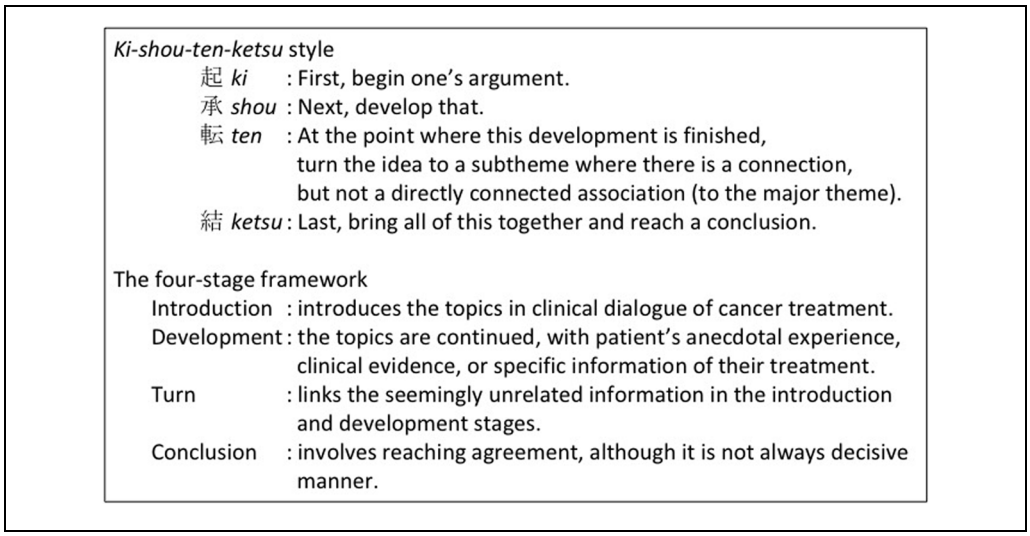

Figure 3. *Ki-shyou-ten-ketsu* style and the four-stage framework in clinical dialogue.
Source. Hinds (1980).

The MTI comprises 10 items, rated on a 7-point Likert-type scale from 1 = *strongly disagree* to 7 = *strongly agree*; total score range is 10 to 70, a range enabling selection of patients with relatively high or relatively low motivation. Example items include ''I want to make the best decision for me'' and ''It's important to strive for advanced medical care.'' The scale was validated with multigroup confirmatory factor analysis among university students, apparently healthy workers, and cancer patients (Hatta et al., 2016).

Once transcripts had been prepared for all 20 patients, we selected two patients with the *highest* and *lowest* overall MTI scores from each cancer group (breast and lung cancer), eight cases in all, to test the working hypothesis. As we transitioned to Phase 3, the analytic strategy was deductive.

Phase 3-QUAL (Both Inductive and Deductive): Detecting the "Four-Stage (Ki-Shou-Ten-Ketsu) Framework.". The authors (TH and KN) separately read and analyzed the eight case transcripts in depth, following the chronological course of the event (i.e., the interaction) and selected 10 or 11 passages (i.e., segments of dialogues of physician–patient interaction) for each case. They then read these passages jointly with the aim of understanding the speakers' attitudes (e.g., psychological distance, intentions), on that basis identified any apparent changes in the patients' motivation (whether in intention, attitude, or subjective norms), and discussed how many passages were relevant to showing the temporal changes in each dialogue.

During the discussion, we applied a rhetorical-analytical framework with four passages, since the four-part organization of a story (*ki-shou-ten-ketsu*) is an important and familiar rhetorical style in Japanese—though rare or nonexistent in English (Hinds, 1980, 1983). In this style, *ki* introduces the topic, *shou* develops the topic, *ten* forms an abrupt transition via a vaguely related point, and *ketsu* concludes the topic (Hinds, 1980, 1983; Figure 3). The analysts selected four of the original 10 passages that demonstrated features of the *ten* stage in each dialogue.

During analysis, the analysts moved continuously back and forth between inductive thinking (developing concepts, categories, and relations from the text) and deductive thinking (testing the concepts, categories, and relations against the text). They identified specific topics from each

passage, organized the passages into *ki-shou-ten-ketsu* style, read the lines again, trimmed the transcripts of all unnecessary content (utterances they deemed unimportant or uninformative), and discussed whether the passage indicated temporal changes in the informed consent consultation. Each case consisted of four stages and about 800 words (with each stage containing around 150 to 200 words; see Appendix B, available in the online version of the article). The framework appears in Figure 3. As we transitioned to Phase 4, the analytic strategy was inductive and deductive.

Phase 4-QUAL (Deductive): Creating Joint Display. To illustrate an integrated interpretation of how the consultations differed between patients with high and low motivation, the quantitative scores and the qualitative framework were merged using a joint display. The authors (TH and KN) designated each stage in each case in *ki-shou-ten-ketsu* style and composed a 150- to 200-word passage describing each stage. This allowed the creation of the joint display, and the authors drew inferences on the function of the turn (*ten*) stage from the observation data and their experiences in the observation.

Study Results

Stylized Dialogues and Impromptu Dialogues

Through observation and peer-debriefing, the authors (TH and KN) found that each oncologist engaged in task-focused behavior to communicate with their patients. There were certain patterns of dialogue (stylized dialogue) in each group, although the chronological order of these dialogue patterns changed with the nature of patients' inquiries and their medical condition (Figures 4 and 5). Although oncologists engaged mainly in task-focused medical exchange, socioemotional interactions such as expression of interest or concern, optimism, empathy, laughter, and joking were also found in the dialogues of each oncologist. Most of these interactions were categorized as impromptu dialogue, as they were sporadic and changed the tone of conversation.

The differences in stylized dialogue between the two types of cancer stemmed from their different clinical contexts. In informed consent consultations with lung cancer patients, the oncologist mainly explained outpatient chemotherapy, ways of contacting individuals during emergencies, and the merits of outpatient treatment (Figure 4). In contrast, with breast cancer patients, the oncologist primarily talked about the current medical state of their cancer, general strategies of cancer treatment, specific strategies for those individual patients, the risks of chemotherapy, and dealing with side effects (Figure 5).

Descriptive Analysis and Case Selection

In the following, we illustrate the results of the QUAN analysis from a methodological perspective. We estimated a feasible sample size was 10 patients from each the lung cancer and breast cancer groups (totaling 20 patients). This sample size allowed us to compare the characteristics of each group as well as to select the participants for the case-oriented analysis (Onwuegbuzie, Johnson, et al., 2009; Onwuegbuzie, Slate, et al., 2009).

The characteristics of the patients and of their informed consent consultations are shown in Table 1. The average age was 60.3 years (SD = 11.1); breast cancer patients were younger than lung cancer patients, t (18) = 5.5, $p < .01$. The average informed consent consultation time was 58.0 (SD = 14.7); consultations for breast cancer lasted longer than those for lung cancer, t (18) = 4.26, $p < .01$. A Mann–Whitney test indicated that breast cancer patients were in an earlier

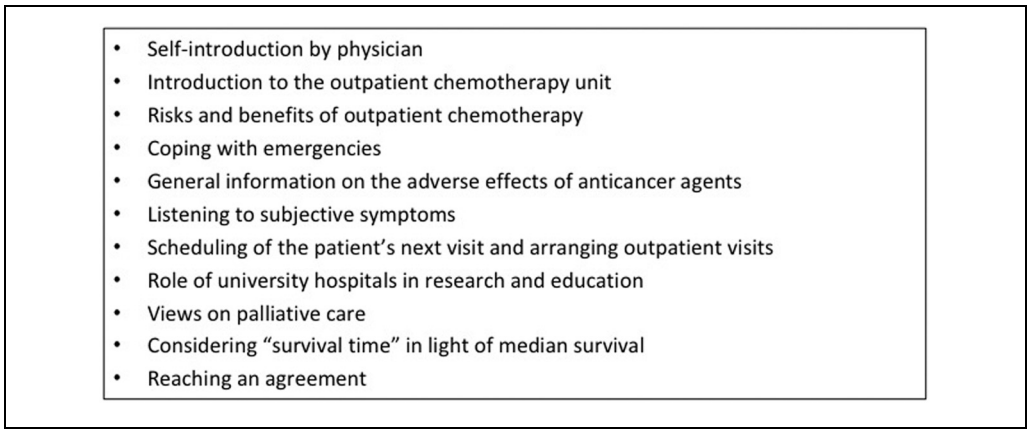

Figure 4. Stylized dialogues during informed consent consultations for lung cancer chemotherapy.
Note. The contents were shown in ordinal chronological order.

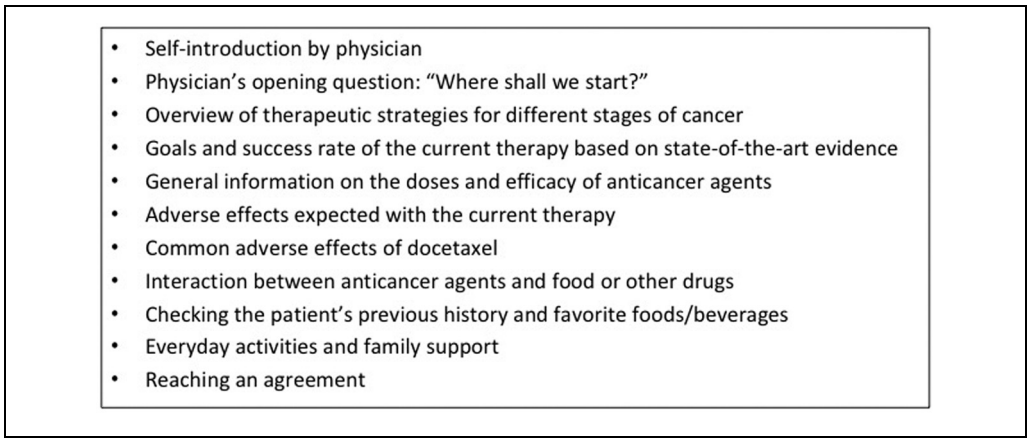

Figure 5. Stylized dialogues during informed consent consultations for breast cancer chemotherapy.
Note. The contents were shown in ordinal chronological order.

stage of the disease on average than lung cancer patients, $U = 17.0$, $p = .01$. The average MTI score was 59.6 ($SD = 8.0$), and both parametric and nonparametric tests did not show significant difference among groups, $t(18) = 1.13$, $p = .27$; $U = 40.5$, $p = .48$.

One role of the quantitative strand of study was to select cases for qualitative analysis (Figure 1). Based on MTI scores, highly motivated patients were selected from the lung cancer (nos. 19 and 24) and breast cancer (nos. 14 and 32) groups, and patients with low motivation from lung cancer (nos. 9 and 12) and breast cancer (nos. 13 and 29) groups. The characteristics of these eight patients and of their informed consent consultations are shown in Table 2.

Four-Stage Framework

The role of the qualitative strand of study was to depict temporal changes in informed consent consultations. Through inductive and deductive analyses, we used the four-stage framework,

Table 2. The Patients' Characteristics and Informed Consent Consultation of the Selected Cases.

Case No.	Patient's		Patient's cancer		Patient's experience of chemotherapy	MTI score	Length of the IC consultation (minutes)	Family presence
	Age	Sex	Type	Stage				
14	50s	Female	Breast	I	nonuse	69	69	Family presence
19	80s	Male	Lung	IV	use	67	49	Family presence
24	60s	Male	Lung	III	use	67	52	Family presence
32	60s	Female	Breast	II	nonuse	66	73	Family presence
13	30s	Female	Breast	II	nonuse	55	70	Family presence
29	50s	Female	Breast	I	nonuse	55	73	Patient only
12	60s	Male	Lung	IV	use	49	46	Patient only
9	60s	Male	Lung	IV	use	34	54	Family presence

Note. MTI = Motivation for Treatment Index; IC = informed consent.

consisting of introduction (*ki*), development (*shou*), turn (*ten*), and conclusion (*ketsu*); they are defined in informed consent dialogue context as below:

1. The *introduction (ki)* introduces topics in clinical dialogue regarding cancer treatment;
2. In the *development (shou)* stage, the topics are continued, and patients' anecdotal experience, clinical evidence, or specific information on their treatment introduced;
3. The *turn (ten) stage* links the seemingly unrelated information in the introduction (*ki*) and development (*shou*) stages; and
4. The *conclusion (ketsu)* involves reaching agreement, although not always decisively (as discussed in Hinds, 1983, p. 190; also see the Discussion below).

As noted above, we documented the cases in under 800 words (with each stage containing around 150-200 words). In the following, we explain the content of each stage using representative passages.

Introduction (Ki) for Case No. 13, a patient with breast cancer. The introduction (*ki*) stage began as oncologists introduced themselves. Oncologists usually inquired about patients' condition and their understanding of cancer treatment, while the patients reported their concerns about chemotherapy. The following passage, from a patient with breast cancer, illustrates this stage:

Doctor (Dr.):	Where shall we start?
Patient (Pt):	I don't know anything about this (laughs).
Dr:	Can I ask you first if there's anything you'd like to ask me?
Pt:	Oh, let's see.
Dr:	Side effects?
Pt:	Yes.

The breast cancer specialist asked the patient open-ended questions and seemed to estimate the patient's understanding of or preparedness for her treatment from her responses. Next, the specialist often gave an overview of treatment (Figure 5). In contrast, following self-introduction and brief introduction of the outpatient chemotherapy unit, the lung cancer specialist often explained matters to which attention was necessary for safe outpatient chemotherapy (Figure 4).

Development (Shou) stage for Case No. 19, a patient with lung cancer. In the development (*shou*) stage, the patients began talking about themselves, including their interest in or experiences of cancer treatment, while the oncologists responded to them. This is represented by the following passage, which occurred after the lung cancer specialist had explained the adverse effects of treatment and had asked the patient about their side effects:

Pt:	Yes, my tongue got sore, but it's not too bad.
Pt's Daughter:	Your tongue is all black.
Pt:	Because I was just eating something.
Dr:	Show me your tongue. Since when?
Pt:	I don't think mouth ulcers are the cause.
Dr:	Sometimes this medicine makes your mucous membranes sore.
Pt:	Ah, I see.
Dr:	Mmm, I don't really want you to think that it's not due to this [the medicine].

During the development (*shou*) stage, oncologists occasionally dealt with painful information or sensitive topics such as survival time (Figure 4). Other types of stylized dialogue found during this stage involved the purpose and success rate of the current therapy and the doses and efficacy of anticancer agents (Figure 5).

Turn (Ten) stage for Case No. 12, lung cancer patient. The focus of the turn (*ten*) stage dialogue was somewhat divorced from the topic of medical treatment. As a representative example, after the lung cancer specialist finished explaining median survival time to a patient (an example of a stylized dialogue in lung cancer), the informed consent consultation entered the turn (*ten*) stage:

Pt:	I mean, (1.0-second pause) aside from this, Can I go back to work? When will that be? Well, 6 months later I suppose.
Dr:	(1.0-second pause) Aha.
Pt:	I don't exactly know. (2.0-second pause) Can you give me your opinion?
Dr:	What were you doing until you were hospitalized?
Pt:	I was working.
Dr:	Aha, you were, weren't you?
Pt:	Yes.
Dr:	The reason I've been treating you as an outpatient is that I believe in letting people work if they are able to work.
Pt:	Yes.
Dr:	(0.5-second pause) Honestly speaking, when you're hospitalized, you get weak.

After the patient, who had been rather reluctant to communicate with his doctor, said ''aside from this,'' he began to carefully talk about his primary personal concern (returning to work), rather than treatment. The oncologist did not quickly answer the question, instead waiting until the patient had finished talking, and then gave a personal opinion on his inquiry—that is, the oncologist's perspective seemed to have shifted during this passage from that of a specialist (focused on medical care and treatment) to that of a fellow-person (with a primary focus on respecting the patient's subjective values and relatability).[1] As shown in the above passage, the turn (*ten*) stage tended to involve the patient's personal interests, unrelated to medical information (and thus to constitute impromptu dialogue).

Conclusion (Ketsu) for Case No. 29, a patient with breast cancer. In the conclusion (*ketsu*) stage, the oncologists and patients reached an agreement. In some cases, their conversation led to convergence in the meaning they attached to chemotherapy—that is, the consultation ended with the oncologist and patient ''on the same page'' (Buckman, 2005), as follows:

Pt:	My son is going to get married this autumn. At first, we were planning to start chemotherapy in spring, but my son decided to do it in autumn. As I heard about the details, I worried about whether I'll be able to attend the wedding (tears).
Dr:	You'll know after you've done it once.
Pt:	I see.
Dr:	Err. (explains about the cycle of the side effects) . . . We can always adjust the dates once you've started.

In this stage, some patients signed the informed consent document immediately, whereas others brought it home to complete and return. Given this emergence of consent at this stage, the authors regarded reaching agreement here as a form of stylized dialogue. This stage differs from the conclusion stage of dialogue in English and other languages (Hinds, 1983, p. 190); see Discussion.

Joint Display

To look at the process of informed consent dialogue in terms of patients' motivation, the authors merged the above-presented qualitative and quantitative results from eight cases. Before creating the joint display, the authors (TH and KN) named each stage in each case using the four-

stage framework and the 150-to 200-word passages describing each stage and arranged the cases in descending order by MTI (Tables 3 and 4).

Introduction (Ki) for Case No. 24, a Patient with Lung Cancer that Demonstrates a Participatory Approach. The passages in the introduction (*ki*) and development (*shou*) stages revealed a correspondence between strength of patients' motivation as assessed by MTI and their proactive participation as detected in the qualitative analysis. This tendency was especially pronounced in the introduction (*ki*) stage, so we will demonstrate this with an example from that stage. The patient (Case No. 24), who had high motivation, was willing to participate in the consultation, as below:

Dr:	You can keep writing in the same notebook that you were given in the ward.
Pt:	Yes, I can easily rewrite it.
Dr:	Well, well (laughs).
Pt:	Don't I have to rewrite it? (laughs).
Dr:	Well, you can use it as it is.
Pt:	Yes.

The patient was referring to a notebook distributed in the university hospital to help patients share with their doctors their health condition and vital signs taken at home. The patient asked if he should copy the admission history information from the previous notebook into a new notebook.

Introduction (Ki) for Case No29, a Patient with Breast Cancer that Illustrates the Omakase (Entrusting) Approach. In contrast to this case, patients with low motivation seemed somewhat vulnerable or passive at the beginning of the informed consent consultation, as below:

Dr:	Where shall we start?
Pt:	My husband has already retired and stays at home, and he was saying that he was going to listen to the discussion with me, but today he has to look after my grandchild, so he told me to go and listen so that I understand everything (laughs).
Dr:	There are lots of things to talk about, so it's better that your husband does come eventually. I don't think you can cope with (1.0-second pause) this treatment all alone.
Pt:	Sorry.

After the oncologist introduced himself and engaged with the patient, the patient quickly disclosed her anxiety about participating in the informed consent consultation without her husband. The oncologist suggested that her family had an important role, and she appeared unprepared to participate in the clinical dialogue without her family. The attitudes of other patients with low motivation also showed hesitancy to participate in or unpreparedness for informed consent consultation, consistent with the omakase model (Slingsby, 2004).

Turn (Ten), Neither Participatory nor Omakase Approach. Although there was consistency between patients' motivation level and their proactive participation in the introduction (*ki*) and development (*shou*) stages, in the turn (*ten*) stage consistency was less clear (Tables 3 and 4). Based on our definitions of each stage and using the deductive approach, we focused on the impromptu dialogue at the turn (*ten*) stage; we elaborate on the meaning of this stage in this light later on.

Conclusion (Ketsu) for Case No. 32, a Patient with Breast Cancer that Illustrates an Omakase (Entrusting) Example. In the conclusion (*ketsu*) stage, regardless of the patient's level of

Table 3. Joint Display Delineating the Temporal Changes of Informed Consent Consultation among Cancer Patients with High Motivation and Interest in Treatment.

Case No.; MTI score; Cancer	Introduction	Development	Turn	Conclusion	Metainfernce of the Turn stage
No. 14; MTI = 69; Breast Cancer	The patient, who came far, showed a good understanding of her cancer.	While discussing the cancer stage, the patient uttered what the oncologist said: "living with cancer."	The oncologist recommended an aggressive chemotherapy for remission.	The oncologist suggested that the patient go back to her hometown and resume a normal life.	The patient coming to terms with her cancer.
No. 19; MTI = 67; Lung Cancer	The patient wanted to be told exactly what his cancer was all about.	The oncologist discouraged the patient from self-judging his conditions.	The oncologist hinted at giving the patient's median survival time, but he was evasive.	The patient said that he was philosophical about his life.	The patient coming to terms with his cancer.
No. 24; MTI = 67; Lung Cancer	The patient volunteered himself to copy his old medical records into a new notebook to which the oncologist declined politely.	In reply, the patient talked about the experience in which he suffered from adverse effects.	Upon the patient talking nonsense about his age, the tense atmosphere of the room was completely wiped out.	The patient's concern about the possibility of ill-judged diagnosis became irrelevant.	An opportunity for the patient to become open about his real concern.
No. 32; MTI = 66; Breast Cancer	The patient described in her own words what was going through in her mind regarding her cancer treatment.	The topic of dysgeusia brought her son's laugh, which made the atmosphere more relaxing.	The oncologist cautioned the patient not to take the current medications.	The patient paused for contemplation 4 times before she could convince herself with the decision.	The patient coming to terms with her cancer.

Note. MTI = Motivation for Treatment Index.

Table 4. Joint Display Delineating the Temporal Changes of Informed Consent Consultation among Cancer Patients with Low Motivation and Interest in Treatment.

Case No.; MTI score; Cancer	Introduction	Development	Turn	Conclusion	Metainfernce of the Turn stage
No. 13; MTI = 55; Breast Cancer	A half-hearted patient's attitudes, and her sister responded to an inquiry from the oncologist instead.	The oncologist informed of the needs for aggressive chemotherapy.	The patient was reluctant to take the proposal.	Realizing the importance of family members to go through the side effects.	The atmosphere became tense, but there was no turn.
No. 29; MTI = 55; Breast Cancer	The patient turned up alone, and the oncologist listened to the patient talking about her anxiety.	The oncologist share the benefits of chemotherapy with the patients.	The patient was mainly concerned about the possible side effects, and the oncologist listened to her.	She revealed the oncologist what was actually behind her anxiety.	An opportunity for the patient to become open about her real interest.
No. 12; MTI = 49; Lung Cancer	The patient was having a defensive attitude.	The patient happened to mention the needle-injection pain.	When the patient began to talk about himself, the oncologist seized the opportunity.	The patient confided in his doctor.	An opportunity for the patient to become open about his real interest.
No. 9; MTI = 34; Lung Cancer	The patient was sounding out his doctor.	The oncologist carefully explained the meaning of median survival time.	The oncologist parted with the patient's median survival time.	The oncologist was led to arranging for outpatient chemotherapy.	The atmosphere became tense, but there was no turn.

Note. MTI = Motivation for Treatment Index.

motivation, the patient and physician reached agreement (in stylized dialogue, where patients were informed and gave their consent). Because all patients gave consent, it is likely that differences in patients' motivation have less of an influence at this stage. The interactions at the stage, however, differed from case to case. Some patients (Cases No. 12, 24, and 29) began to relate personal interests or concerns not related to medical treatment only at this stage. Other patient (Case No. 32, a breast cancer patient) committed to their choice for treatment through long silences, as below:

Dr:	Is there anything you don't understand so far? (6.0-second pause)
Pt:	I'll ask whenever I think of something.
Dr:	Yes. There are some people who bet (3.0-second pause) . . . on a 50% chance [that is the chance of successful treatment] with an operation alone.
Pt:	But the previous doctor said, he can't bet on a one-half probability, because that's a hard place to reach.
Dr:	Aha.
Pt:	We'll have to do it, I think.
Dr:	Aha (4.0-second pause)
Pt:	I understand.
Dr:	Yes (4.0-second pause) (Looking at the patient's son) Is there something else?
Pt's Son:	No.
Dr:	Isn't there anything else?
Pt:	No.

In the above exchange, the oncologist maintained a wait-and-see attitude. Nagaoka et al. (2013) investigated silence in clinical dialogues in a Japanese psychotherapy context where therapists gave their clients plenty of time to focus on their internal process, and discussed its implications. Such nonverbal communication might help maintain harmonious relationships (Kakai, 2002; Saldov et al., 1998) or even help secure agreement to a course of treatment.

Discussion of Study Findings

This study implemented crossover-tracks analysis in a convergent design. Using this design, we identified the four-stage framework in informed consent dialogue: introduction (*ki*), development (*shou*), turn (*ten*), and conclusion (*ketsu*). During the first two stages, patients with higher motivation and interest in treatment showed greater interest in participating in the dialogue than those whose scores were lower. These differences lessened during the turn (*ten*) and conclusion (*ketsu*) stages.

Selecting the Framework of Dialogue

Ki-Shou-Ten-Ketsu Style. This style greatly influenced our analytical approach and materials; for example, we chose the passages in each stage so that the turn (*ten*) could be seen clearly in the dialogue. This leads to overlap in stylized dialogues among the stages (e.g., ''considering survival time in light of median survival,'' a stylized dialogue for lung cancer detected at the development (*shou*) and turn (*ten*) stages) and also influences our analytical materials (e.g., the 800-word description of an informed consent consultation; see Appendix B, available in the online version of the article).

Moreover, the authors conducted the analysis and discussion in Japanese and then translated the data into English. The different rhetorical styles between these two languages may be important especially at the conclusion (*ketsu*) stage. Hinds (1983, p. 190), translating Takemata (1976, pp. 26-27), said of Japanese compositions that ''The conclusion need not be

decisive. All it needs to do is to indicate a doubt or ask a question.'' Although his discussion does not apply entirely to our analysis, as he was writing about newspaper essays on daily life and we are discussing clinical dialogues, it does not seem easy to interpret the agreements between the oncologists and their patients without arriving at something close to our interpretation. Given that all patients signed the consent form for outpatient chemotherapy either there-and-then or later on, we regard them and the doctors as having reached agreement, even though the interactions involving that agreement differed from case to case, as above. Thus, the conclusion (*ketsu*) stage involves ''reaching agreement, although not always in a decisive manner.''

Although the Japanese context makes it reasonable to select the *ki-shou-ten-ketsu* style, which should be natural for most Japanese people, rhetorical differences in language and epistemological/cultural differences exist between East Asia and elsewhere. As Bankier (2014) mentioned, Cahill (2003) found that rhetorical styles in Japanese were in general not unlike those of English, while Kobayashi and Rinnert (2002) found that Japanese writing education was moving toward a style of writing similar to the Western academic mode (Bankier, 2014). As discussed in Bankier (2014), however, many researchers (Donahue, 1998; Guest, 2001; Kubota, 1997, 1999) emphasized that beliefs about the distinctness of Japanese writing remain influential. *Ki-shou-ten-ketsu*, which originated in classical Chinese poetry, is an expository prose style that both Japanese and Korean imported from China (Hinds, 1980, 1990). Previous works have investigated how Japanese epistemological/cultural perspectives involve the clinical practice or applied linguistics research (Kubota, 1997, 1999; Long, 2000; Saldov et al., 1998); however, to delineate how they influence research methods or results, mixed methods studies across East Asian cultures are needed.

Meta-Inference on the Function of the Turn (Ten) Stage

We focused on the turn (*ten*) stage because this stage represented a *turning point* in the consultation in several cases, that is, a ''sudden change of quality that plays the part of a forerunner or prerequisite to slow structural change in psychometric treatment'' (Bohm, 1992). This perspective allowed us to draw meta-inferences on the function of the turn (*ten*) stage for each case (Tables 3 and 4). For example, it was at the turn (*ten*) stage that one patient began to talk about himself, at which point the oncologist seized the opportunity to help the patient express his real interest (Turn Stage for Case No. 12). This patient had seemed to be a ''difficult patient'' until disclosing his own wish at this stage (see Appendix B, available in the online version of the article); the function of the turn in his case thus emerged as an ''opportunity for the patient to become open about his real interest.'' This type of function was observed in other cases as well (Nos. 24 and 29), regardless of the strength of the patient's motivation. Highly motivated patients seemed willing to accept that they were suffering from cancer after the oncologists informed them of the seriousness of their condition (Nos. 14, 19, and 32), which was an attempt by the oncologists to direct the patients to seek agency (Schwandt, 2014). Based on this interpretation, the function of the turn (*ten*) stage in these cases could be expressed as ''the patient coming to terms with his/her cancer.'' Conversely, we identified a third, corresponding function: ''the atmosphere became tense, but there was no turn''—that is, patients did not open their heart to their oncologists (Cases No. 9 and 13) during the limited period of the informed consent consultation. While the oncologists tried to approach the patients, they often found themselves struggling to elicit the patients' agency.

Limitations

Generalizability. This study was conducted in a university hospital, meaning that patients might have been seeking more specialized chemotherapy treatments or might have been more motivated for treatment. Japanese patients' motivation in general may be lower than in this study. As patients who their oncologist deemed to be at psychological risk were excluded from the study, there may have been selection bias for patients who would be most open to frank dialogues with their oncologists. Moreover, the oncologists in this study were unusually well trained in task-focused and socioemotional communication (Roter & Larson, 2002). Thus, the sample may have been skewed.

Confounding Factors. One possible factor is type of cancer—oncologists' explanations to patients of course vary depending on type of cancer, which could lead to differences in the temporal flow and development of the dialogues. Indeed, we detected differences in both information for particular topics and temporal order of topics, both between and within the oncologists (Figures 4 and 5). As another possible factor, family plays an especially critical role in diagnosis disclosure, treatment decision, and caregiving in Japan (Akabayashi, Fetters, & Elwyn, 1999; Fetters, 2015; Long, 2000; Long & Long, 1982); thus, presence or absence of family members could influence the interaction. In addition, patients' sex, age, cancer stage, and experience of chemotherapy stand as potential confounds that we did not investigate. If our analytical approach had relied on an experimental procedure, as does, for instance, the Roter Interaction Analysis System (Roter & Larson, 2002), we would have identified these confounding factors and evaluated the size of their effects using inferential statistics. This approach may also investigate the relations between those factors and patients' interest in participating in the dialogue. In this study, however, the focus of our analysis was instead on delineating temporal changes in clinical dialogues of around 60 minutes, which yielded four temporal stages; to support the internal validity of the interaction patterns found at each stage, it remains necessary to investigate passages within and between stages using quantitative or mixed methods analysis.

The Credibility of the Qualitative Analysis. To avoid interfering with the natural clinical setting and the oncologists' communication styles, the observer (TH) never asked oncologists about their intentions or meaning during the consultations and did not confirm whether patients trusted their oncologist. This lack of confirmation might have led to a gap between speakers' intentions and our interpretations. To minimize any problems caused by gaps in intention, the first and second authors engaged in debriefing after each observation.

Clinical Implications: The Concept of Informed Consent in Japan

Our study hypothesis was that the informed consent dialogues of patients with higher motivation and interest in treatment would reflect a greater interest in participating in the dialogues compared to those of patients with lower motivation and interest in treatment. In our mixed methods analysis, we confirmed this hypothesis at the beginning of the dialogues and refuted this hypothesis at the end of the dialogues. Based on the *ki-shou-ten-ketsu* model of analysis, by the end of physician–patient dialogues, we find evidence that even patients with initially lower motivation became more highly motivated. The Japanese physician–patient relationship as manifested by the clinical dialogue analysis in this setting illustrates there has been a shift from the omakase (entrusting) model to a participatory model (Slingsby, 2004), and this shift can be seen in the examples above. With the promotion of outpatient chemotherapy and expectations for the quality of the informed consent process (MHLW, 2007, 2012), patients are now expected to take

greater interest in their treatment prior to starting informed consent consultation. In this social context, we demonstrate that given an ''opportunity for the patient to become open with real interest'' that it will emerge, regardless of the strength of the patient's initial interest. It is notable that this human activity emerged in the context of medical informed consent, derived from both the physician and the patient, who share an interest in realizing the best possible clinical conduct (Yanagida, 1996). This sheds light on a shift in the meaning of informed consent in Japan.

Contribution to Mixed Methods Research

The Novel Point Established by This Study. In the hypothetico-deductive method, hypotheses about behavior are logically deduced from theory and tested through empirical observation (Schwandt, 2014). We implemented analytical switches between inductive and deductive approach during the study. This process occurred naturally in response to the study needs and progression. This research also extends the dialogue about three levels of analysis, the relational dimension, the methodological dimension, and the directional dimension in convergent designs as raised by Moseholm and Fetters (2017). In the relational dimension separative versus iterative (compare with the parallel-tracks vs. crossover-tracks analysis), our example is iterative. Relative to the methodological dimension, qualitatively driven, quantitively driven, or equivalently driven, our example illustrates a qualitatively driven approach. In the directional dimension, unidirectional versus bidirectional, importantly, our example demonstrates a highly dynamic bidirectional process, even than they describe. Moreover, we illustrate explicitly the dynamic switching back and forth between the inductively and deductively driven analysis.

Our working hypothesis was derived from literature review of Japanese context on medical informed consent. The study hypothesis was that the informed consent dialogues of patients with higher motivation and interest in treatment would reflect a greater interest in participating in the dialogues compared to those of patients with lower motivation and interest in treatment. Although the hypothetico-deductive method ordinarily uses an experimental design and quantitative methods to test a hypothesis through deductive reasoning (Frost & Shaw, 2015), this hypothesis allowed us to implement both qualitative and quantitative inquiry alongside the qualitatively driven mixed methods approach in our study with a small sample size.

The procedures of our empirical observations are illustrated in Figure 1. There were at least two levels of integration during data collection and analysis, connecting and merging, where we used both hypothetico-deductive methods, that is, the shift from inductive analysis for exploring all cases to deductive analysis for proving the working hypothesis, and case-oriented analysis, that is, the dialogue analysis using the *ki-shou-ten-ketsu* framework (Onwuegbuzie, Johnson, et al., 2009; Onwuegbuzie, Slate, et al., 2009).

Caveat on Mixed Methods Design. It behooves us to mention that the sampling process in this study posed a methodological limitation. Teddlie and Yu (2007) suggest that the sampling strategy in a concurrent mixed methods design (convergent design) should depend on how researchers actually combine probability and purposive sampling, with reference to both a study collecting both qualitative and quantitative data independently (Lasserre-Cortez, 2006) and a survey implementing open- and closed-ended questions concurrently (Parasnis, Samar, & Fischer, 2005). However, our sampling strategy was modified from these mixed sampling strategies, in that it consisted of two steps: purposive sampling of 20 patients in the university hospital, and selecting 8 patients from among them for qualitative analysis.

Regarding this selection process, which had the potential to induce bias, we should mention the implications for the study of the 12 patients not selected. Without them, we could not have identified the stylized dialogues and characteristics of breast cancer oncologists compared to those of lung cancer oncologists. All 20 cases were essential to compare the oncologists' strategies in their clinical dialogues. Since these less distinctive cases have less illustrative value than the ones selected, however, we refrain from discussing them further here given space constraints.

Our research design made it difficult for us to collect cases for in-depth analysis to the point of saturation, because the cases were quantitatively determined before the qualitative analysis. It should be noted that such a mismatch between the sampling and analysis methods may threaten the credibility of the qualitative results in mixed methods study. This then implies that the connecting function in an explanatory sequential design could also pose the same contradiction between sampling and analytical strategy, if the researcher pursues rigorous procedures in both the qualitative and quantitative strands.

Conclusion

This study implemented crossover-tracks analysis with a hypothetico-deductive method in a convergent design to examine a working hypothesis related to clinical dialogues about cancer treatment in Japan. We estimated the strength of patients' motivation to participate in informed consent consultation, identified a four-stage (*ki-shou-ten-ketsu*) framework depicting temporal change in the dialogues, and delineated how the dialogues differed between patients with high and low motivation. Methodologically, the study illustrates the dynamism of hypothetico-deductive methods during a crossover analysis in a convergent design. We hope these findings will encourage further examination of theory-based research about informed consent in Japan, while also inviting further dialogue on the dynamic analytical possibilities in convergent designs.

Acknowledgments

We would like to express our heartfelt thanks to all patients who participated in the study. The authors wish to acknowledge Dr J. W. Creswell for his innovative suggestions that enabled us to interpret the significance of this study from a different angle. We are very grateful for the constructive comments of anonymous reviewers and the editors. We thank Hidenori Kashihara, MPH, Takashi Mitamura, PhD, Misa Inoue, MA, and Seiji Saito, MD-PhD for their practical feedback. We also thank Editage for providing editorial assistance.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by JSPS KAKENHI (Grant Nos. JP23790568 and JP 26870311), the Foundation for Promotion of Cancer Research, the Kyoto Cancer Society, the Pfizer Health Research Foundation, and the Uehiro Foundation on Ethics and Education.

Note

1. In the short interview immediately after the consultation (No. 12), the oncologist mentioned his father, who had kept working despite enduring health problems.

Supplemental Material

The online supplemental material is available at http://journals.sagepub.com/doi/suppl/10.1177/1558689818792793

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Online Appendix-A

Consent Form

Title: Participant observation study of informed consent for outpatient chemotherapy

To the director of the hospital,

I have been given an explanation according to the explanatory document about the above study. Having fully understood the explanation, I gave my consent of my own free will to participate in the following option of research (Please tick either for the relevant box below):

□ I shall give my consent to respond the questionnaire only.

□ I shall give my consent to cooperate the participant observation and the questionnaire.

*I understand that even if I consent to participate in the study, I am free to withdraw my authorization at any time.

*I received a copy of the signed consent form.

■ Date of consent:_____/_____/_____(Year/ Month/ Day)

Participant (patient in person):_____(Signature)

■ Date of explanation:_____/_____/_____(Year/ Month/ Day)

Physician providing explanation:_____(Signature)

Researcher providing explanation:_____(Signature)

Online Appendix-B

An example of an 800-word description of an informed consent consultation: Case No. 12, a lung cancer patient with low motivation.

Before the informed consent consultation: Delineation from field notes.

The patient (Mr. E) was a 60-year-old lung cancer patient who had experience of inpatient chemotherapy at a university hospital. He came alone into the outpatient chemotherapy unit form the hospital ward. He met with the oncologist and the observer for the first time. When the observer asked him to participate in this study, he seemed to be cranky, made an intimidating face, and turned his name card back to front. The observer's first impression of him was that "he will never accept my proposal and never listen to me."

Introduction (*Ki*) stage: The patient was having a defensive attitude.

Dr: On the day of a drip, I'd like you to measure your blood pressure and your weight at Reception [i.e., the waiting room] like just now.

Pt: Yes.

Dr: And

Pt: Mmm (coughs).

Dr: If you didn't measure your temperature at home, I'll give you a thermometer, so please say if you need one.

(Doctor notices the patient's name card is back to front)

Dr: Err, it's back to front (laughs).

(Doctor approaches the patient and is trying to take out the name card from the case).

Pt: Mmm (coughs).

Dr: Well, in the waiting room it can be back to front.

Pt: Mmm (coughs).

Dr: Well, when you're having the drip, I'd like you to show [the front side] to the front. Because even if Mr. E falls asleep during a long drip, the nurse will recognize that you are Mr. E, and she can change over to the next [visiting patient]. Please cooperate.

Development (*Shou*) stage: The patient happened to mention the needle-injection pain.

Dr: When you had a drip, I saw that your card [i.e., electronic medical chart] said, it was painful where the needle was inserted. Did you have any pain?

Pt: (1.0-s pause) Well, that was a physical thing. (laughs) The needle wasn't inserted properly.

Dr: Ah (laughs).

Pt: It was painful.

Dr: Ha ha ha.

Pt: I think that was probably the reason.

Dr: Today, how was it? Today's drip?

Pt: (1.0-s pause) Today, I had no particular problem.

Dr: You didn't have any problem?

Pt: Yes.

Dr: There are some patients who complain of pain along the vein with this medication. But, as you say, it depends on how the needle is inserted. That's why it might have been painful. If you had no problem today, I think we can say there's no problem. If you come to Outpatients.

Pt: Yes (small voice).

Dr: At the beginning, if it often happens, I'll have to get them to deal with it.

Turn (*Ten*) stage: When the patient began to talk about himself, the oncologist seized the opportunity.

Dr: That's everything I wanted to say, but do you have any questions?

Pt: Well, let me think.

Dr: Aha.

Pt: I mean, (1.0-s pause) aside from this, Can I go back to work? When will that be? Well, 6 months later I suppose.

Dr: (1.0-s pause) Aha.

Pt: I don't exactly know. (2.0-s pause) Can you give me your opinion?

Dr: What were you doing until you were hospitalized?

Pt: I was working.

Dr: Aha, you were, weren't you?

Pt: Yes.

Dr: The reason I've been treating you as an outpatient is that I believe in letting people work if they are able to work.

Pt: Yes.

Dr: (0.5-s pause) Honestly speaking, when you're hospitalized, you get weak.

Pt: Yes.

Dr: So, really, I'd like you to let you leave the hospital as soon as possible. Leaving the hospital is, basically, getting back to the normal routine.

Pt: Mmm (coughs).

Dr: I think so.

Conclusion (*Ketsu*) stage: The patient confided in his doctor.

Dr: What do you do for a living?

Pt: I'm a security guard in a supermarket.

Dr: If that's a place where there are a lot of germs, it wouldn't be a good idea. But I'd like you to go back to work as usual if possible.

Pt: Ah, I see.

Dr: But, since you were hospitalized for a long time, I honestly think it's a bit tough to go back to work suddenly.

Pt: Umm (laughs).

Dr: I think it'd be good if they could shorten your working hours. That might be difficult in today's working environment. I think that basically you can go back to work as usual.

Pt: Ah, I see. (4.0-s pause) Fortunately, I got a message saying, come back as soon as you can.

Dr: Yes.

Pt: Even in today's hard world.

Dr: Yes, really.

After the informed consent consultation: Delineation from short interview and field notes.

The observer asked the patient (Mr. E) to provide free comment on the dialogue. He responded (in a very free translation, for sense rather than literal meaning of the

words), “I could basically understand the things [the doctor said]. I could get the answers I wanted, and avoid hearing the doctor say what I did not want.”

The observer also asked the oncologist to provide free comment on the dialogue. The oncologist responded, “Although his face was stiff at the beginning, it was nice to hear his story at the end. To be honest, I did not expect you to get his permission for participant observation, hahaha.” Moreover, the oncologist mentioned his father, who had kept working despite enduring health problems—as the patient wished to do.