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Protocol of an iterative qualitative study to develop a molecular testing decision aid for shared decision-making in patients with lung cancer after surgery

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ABSTRACT

Introduction Although molecular testing is crucial for many patients with lung cancer, the decision to carry out molecular testing is not easy to make in actual clinical scenarios. Using a specific decision aid (DA) to conduct shared decision-making (SDM) may help ameliorate this problem. However, no DA currently exists for lung cancer molecular testing (DA_LCMT). We aim to develop an evidence-based, iteratively refined DA, which may facilitate SDM and improve the quality of SDM.

Methods and analysis After considering the Ottawa Decision Support Framework, International Patient Decision Aid Standards and Food and Drug Administration guidance about methods to identify what is important to patients, semistructured interviews with qualitative research methods will be used to generate the decision-making needs of patients with lung cancer diagnosed with lung adenocarcinoma by intraoperative frozen pathological sections. Input will be provided by patients and other stakeholders, including thoracic surgeons, nurses, hospital administrators, molecular testing company staff and insurance company staff. Then, a modified Delphi method will be used to develop the DA_LCMT V.1.0 (DA_LCMT 1.0). Structured interviews with qualitative research methods will be used in the cognitive debriefing (alpha tests) and field testing (beta tests) to revise and improve the DA_LCMT from version 1.0 to the final version, version 3.0. Descriptive statistics will be used to summarise the baseline characteristics of the patients and other stakeholders. Qualitative data will be analysed using the three steps of grounded theory: generate a codebook, update the codebook and create a comprehensive list of related items.

Ethics and dissemination Ethics Committee for Medical Research and New Medical Technology of Sichuan Cancer Hospital approved this study. This protocol is based on the latest version 1.0, dated 31 October 2021. The study was also approved by the Ethics Committees of The Third People's Hospital of Chengdu, Zigong First People's Hospital and Jiangyou People's Hospital. The results of this study will be presented at medical conferences and published in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is an evidence-based, iterative, multicentre, prospective study in a real-world clinical setting in China.
⇒ The development and improvement of a decision aid will be conducted according to the international standard Ottawa Decision Support Framework, International Patient Decision Aid Standards and Food and Drug Administration guidance.
⇒ The decision aid will be derived directly from the perspective of patients with lung cancer and other stakeholders; its comprehensibility and usability will be assessed through multiple iterative tests, including cognitive debriefing and field testing.
⇒ One-to-one interviews will be used for in-depth information mining, although they are associated with increased workload.
⇒ As a multicentre study, the geographical distance between participating centres requires additional resources to ensure data quality.

Trial registration number NCT05191485.

INTRODUCTION

According to the National Comprehensive Cancer Network guidelines[1] and consensus recommendations of Chinese experts,[2] patients with non-small-cell lung cancer who are pathologically diagnosed with lung adenocarcinoma or lung cancer containing adenocarcinoma should ideally receive routine molecular testing. Molecular testing can detect gene mutations, such as epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase gene mutation. This can help clinicians select appropriate targeted therapy for patients[3] and make timely adjustments to medication regimens according to the test results, to develop the most beneficial

individual treatment regimens for patients.[1 2 4] Compared with adjuvant chemotherapy, adjuvant targeted therapy can reduce the toxicity and side effects of postoperative treatment, improve patient compliance with postoperative adjuvant therapy and significantly enhance the prognosis of patients with lung cancer.[4–7] Accurate detection of gene mutations is crucial for individualised therapy guided by genotyping, and is a prerequisite for improving the benefits received by patients in targeted therapy.[1 2] The EGFR gene mutation appears in as much as 50% of the Asians.[5 8 9]

However, the application of lung cancer molecular testing remains low globally, with less than half of all patients estimated to currently receive such testing.[10] There are several challenges to implementing molecular testing in clinical practice, including high cost, low testing quality, high reliance on external testing laboratories, insufficient testing awareness among clinicians and long wait-time for test results.[10] Both clinicians and patients are dissatisfied with the current state of molecular testing in lung cancer. More than one-third of clinicians are concerned about testing quality and reliability.[10] Meanwhile, most patients have difficulties understanding the test results, which are often reported to them directly from external laboratories instead of clinicians.[11]

Molecular testing is usually conducted after the diagnosis of lung adenocarcinoma. Thoracic surgeons can remove lesions and pathologists can diagnose lung adenocarcinoma through intraoperative frozen section pathology.[12–16] However, in actual clinical settings, the decision to carry out molecular testing is not easy to make. The clinical workload is considerable, and there are often great differences in understanding of the importance and reliability of molecular testing among medical staff, patients and their families.[17] Because of the pressure and uncertainty, this decision has always been a burden for both clinicians and patients.

Shared decision-making (SDM) has been proposed within the medical community for many years; although it has not been routinely used in clinical practice,[18–21] it may provide a better approach to the aforementioned scenarios. SDM is the process by which patients and clinicians learn about the benefits, harms and effectiveness of healthcare testing and treatments, identify personal priorities and values, and agree on a course of action.[22 23] SDM can help combine healthcare with patients' preferences and values, and minimise issues faced by patients, family members and healthcare providers.[22] It can enable healthcare providers better fulfil their obligation to inform, closely listen to patients and their families, and be truly patient-centred.[18] Based on individual cases, a detection scheme should be jointly formulated to provide a solid foundation for possible follow-up treatments and to ensure better prognosis.

Decision aids (DAs) are often used to facilitate the implementation of SDM. Patients require assistance in making a high-quality decision, informed by the best available evidence and grounded in personal values.[24 25] DAs are evidence-based tools designed to inform patients about their options (including known pros and cons) and help them participate in making specific, deliberate choices from viable healthcare options.[26] They support patients' participation in decision-making when there is more than one reasonable option, with different features that patients may value differently.[27–29] Typically, DAs that are developed using the Ottawa Decision Support Framework (ODSF) prepare patients for deliberations with their practitioner by making the decision explicit and guiding patients in a series of steps.[30–33] However, to date, there are no DAs for lung cancer molecular testing (DA_LCMT).[20]

In this study, we aim to develop an evidence-based, iteratively refined DA to identify patient preferences for DA_LCMT, following the guidance from the ODSF,[30] International Patient Decision Aid Standards (IPDAS)[29 34 35] and the Food and Drug Administration (FDA).[36] The DA will contain three parts. The first, decision-making, will present and explain the decisions we need to make and why we need to make these decisions. The second, decision options, will consider the advantages and disadvantages, and risks of each decision option, including detailed enumerations and a brief summary. The third, decision support, will consider possible issues to be discussed with medical personnel and required decision support. This DA may facilitate SDM regarding the decision to conduct molecular testing for patients diagnosed with lung adenocarcinoma by intraoperative frozen pathological sections and may provide an approach to improve the quality of SDM. We also plan to evaluate the effectiveness of the developed DA by conducting a follow-up randomised controlled trial (RCT). The RCT protocol has been reviewed and approved by our ethics committee and will be published in the near future.

METHODS AND ANALYSIS

Study design

This study will be the first part of a multicentre study named CN-SDM-Lung 1 part I, which will use evidence-based DA development methods, including qualitative methods and iterative stakeholder engagement, to develop and refine a DA named DA_LCMT. Guided by the ODSF, IPDAS and FDA, we will first conduct semistructured interviews with target patients, patient representatives and other stakeholders (including thoracic surgeons, nurses, hospital administrators, molecular testing company staff and insurance company staff) to assess decisional needs. The handbook for semistructured interviews with patients and other stakeholders will focus on the perspectives of patients and other stakeholders, respectively. We plan to assess decisional needs including difficult decision type/timing, unreceptive decisional stage, decisional conflict (uncertainty), inadequate knowledge and unrealistic expectations, unclear values, inadequate support and resources, and personal and clinical needs. All interviews will be conducted one-on-one or one-on-many (including

families) and audiorecorded for further analysis. Written informed consent will be obtained prior to each interview. Then, an iterative process will be used to code the interview transcripts and to identify the items that relate to patients' and other stakeholders' decisional needs. Using modified Delphi panel methods, all items will be revised to improve the draft of the DA_LCMT and generate the DA_LCMT 1.0.

Cognitive debriefing (alpha test) will be implemented in order to test the comprehensibility of the DA_LCMT 1.0.[37] All debriefing interviews will be conducted one-on-one and written informed consent will be obtained prior to each interview. Cognitive debriefing will be conducted using a predefined interviewer protocol with structured probing questions. Participants will be encouraged to comment on the DA_LCMT 1.0, and to give recommendations for the replacement of any unclear wording. First, the interviewer will explain the aim of the study and the cognitive debriefing procedures to the participants. Then, a paper-based DA_LCMT 1.0 and a pen will be given to participants, and sufficient time provided to allow them to read the DA_LCMT 1.0 and to write down their comments and suggestions. The cognitive debriefing interview will start afterwards; the participants will answer probing questions asked by the interviewers about the DA_LCMT 1.0. Each cognitive debriefing interview will last for approximately 20 min. The DA_LCMT 2.0 will be generated after completion of the cognitive debriefing (alpha test).

Then, the investigators will conduct field testing (beta test), in which the patients and clinicians use this aid in clinical practice.[37] The purpose of the beta test is to examine the usability of the DA_LCMT 2.0 in a 'real-world setting.' Clinicians and patients will use the DA_LCMT 2.0 for real time decision-making, and the conversation of the entire decision-making progress will be audiorecorded. After the decision is made by the patients, structured interviews will be conducted and audiorecorded separately between clinicians and patients by the investigators. All field testing interviews will be conducted one-on-one and written informed consent will be obtained prior to each interview. The structured probing questions of the Beta testing interview are based on the predefined interviewer protocol. Each field testing interview will last for approximately 20 min. After the field testing (beta test) of the DA_LCMT 2.0, the final version of the DA, the DA_LCMT 3.0, will be generated. A flow diagram of the study is shown in figure 1.

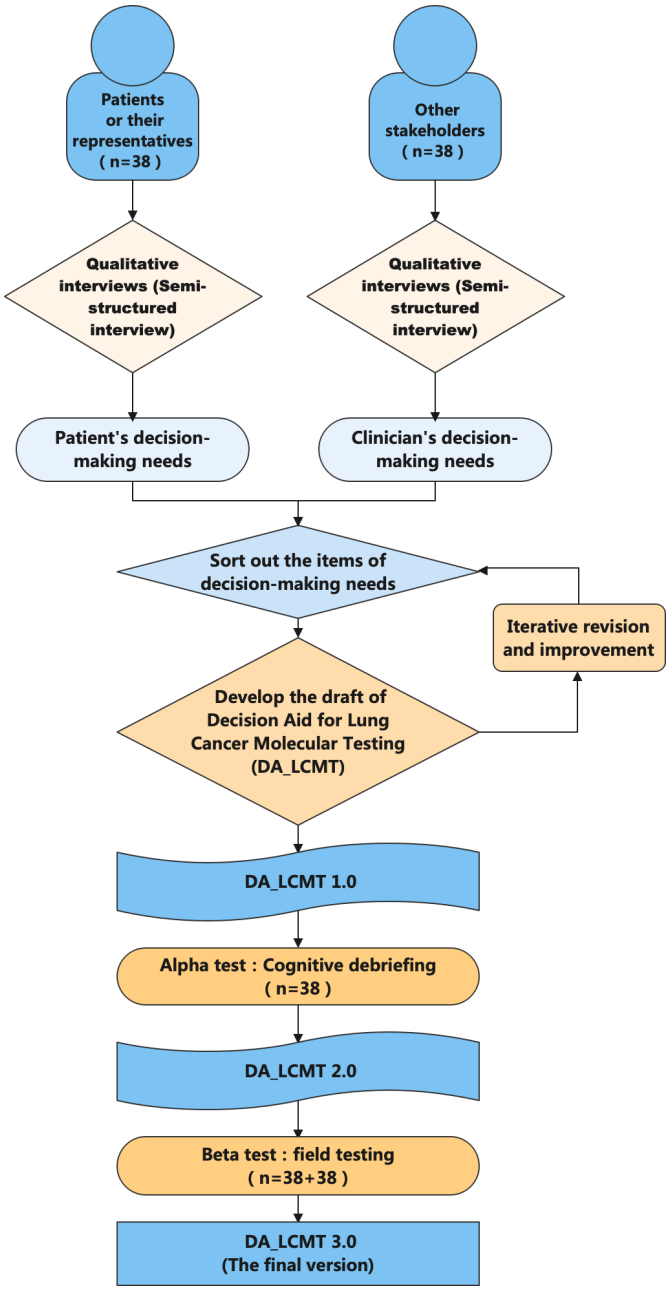

Figure 1 Flow diagram of this study. DA_LCMT, Decision Aid for Lung Cancer Molecular Testing.

Setting

This study will be conducted in four hospitals in China: Sichuan Cancer Hospital, the Third People's Hospital of Chengdu, Zigong First People's Hospital and Jiangyou People's Hospital. This study was initiated at the Sichuan Cancer Hospital and scheduled to start in February 2022. It is estimated to be completed by 31 December 2022.

Study population

Non-random purposive sampling will be used to select key respondents to participate in in-depth interviews. Snowball sampling, in which potential participants are asked to identify others who may be willing to participate, as well as convenience sampling, will be used. For patients, we will aim for diversity regarding age, sex, education level and annual household income. For other stakeholders (including thoracic surgeons, nurses, psychoanalysts, hospital administrators, molecular testing company staff and insurance company staff), representativeness in region, seniority, position and attitude towards both molecular testing and SDM will be considered. All participants must speak Chinese.

Sample size estimate

By referring to other literature[38 39] and in order to achieve information saturation as far as possible, it is preliminarily estimated that data from approximately 30 cases must be included in the final analysis. Considering that approximately 20% of the data may not qualify for final analysis, data from at least 38 cases are needed in each section of the study. That is, at least 38 patients with lung adenocarcinoma after surgery and 38 other stakeholders will need to be interviewed in the decision-making need assessment section. In the section on cognitive debriefing (Alpha tests), at least 38 patients or their authorised representatives need to be enrolled. In the field testing section (beta tests), at least 38 patients are required, and 38 clinicians will need to use the DA_LCMT 3.0 to make shared decisions and be interviewed in real time separately.

Decisional needs assessment

There will be two subphases: Subphase no. 1 will consist of semistructured interviews with qualitative research methods to generate the decision-making needs of patients and other stakeholders and subphase no. 2 will consist of a modified Delphi method, which will be used to develop the untested version of the DA_LCMT 1.0.

Inclusion criteria for patients

Inclusion criteria are as follows: (1) age ≥18 years; (2) patients with primary invasive adenocarcinoma of the lung diagnosed by intraoperative frozen pathological section and (3) have or have not made a decision on lung cancer molecular testing (whether to receive molecular testing or not).

Exclusion criteria for patients

There is one exclusion criterion: inability to understand the research content.

Inclusion criteria for other stakeholders

Inclusion criteria are as follows: (1) age ≥18 years; (2) relevant work experience ≥2 years; (3) for thoracic surgeons and personnel in molecular testing companies: previous experience in communicating with patients about molecular testing related to lung cancer targeted therapy; for nurses, hospital administrators and personnel in insurance companies: understanding of the decision-making process; and (4) voluntarily participating in this study.

Exclusion criteria for other stakeholders

There is one exclusion criterion: inability to understand the research content.

Withdrawal criteria for patients

Withdrawal criteria are as follows: (1) the participant has serious postoperative complications and is unable to participate in the interview or cooperate to complete the study; (2) the participant fails to cooperate with the semistructured interview according to the interview outline of the research scheme; (3) the participant is unable to express their views clearly during the interview; (4) the participant does not comply with the study plan; (5) the participant asks to withdraw from the study and (6) the investigator identifies other situations requiring withdrawal from the study.

Withdrawal criteria for other stakeholders

Withdrawal criteria are as follows: (1) the participant fails to cooperate with the semistructured interview according to the interview outline of the research plan; (2) the participant is unable to express their views clearly during the interview; (3) the participant does not comply with the study plan; (4) the participant asks to withdraw from the study and (5) the investigator identifies other situations requiring withdrawal from the study.

Data analysis

Audiorecordings of the decision-making conversation will be professionally transcribed by a third-party transcription provider. Then, the qualitative data will be analysed using the three steps proposed by the grounded theory.[38 40] First, we will use NVivo V.12 software (QSR International, 2020; http://www.qsrinternational.com) to automatically capture words and manually code them through judgement, annotation and classification to generate a primitive decision needs codebook, based on the ODSF Definitions (Revised 2020).[31] Then, the original codebook will be updated by adding new decisional need-related words, removing duplicated words and combining similar words through an expert panel. Next, two researchers will independently encode the same transcript (two transcripts in total) using the updated code book. In case of discrepancy, consensus will be reached after discussion with a third researcher. The frequency and number of decision-making need items and the number of participants will be extracted from the transcript. Finally, a comprehensive list of decisional need-related items will be generated.

Cognitive debriefing (alpha test)

Cognitive debriefing will be conducted using a predefined qualitative interviewer protocol with structured probing questions to test the comprehensibility of the DA_LCMT 1.0.[37]

Inclusion criteria for patients

Inclusion criteria are as follows: (1) age ≥18 years; (2) patient with primary invasive adenocarcinoma of the lung diagnosed by intraoperative frozen pathological section and (3) has made a decision on whether to perform lung cancer molecular testing.

Exclusion criteria for patients

There is one exclusion criterion: inability to understand the research content.

Inclusion criteria for other stakeholders

Inclusion criteria are as follows: (1) age ≥18 years; (2) relevant work experience ≥2 years; (3) for thoracic surgeons and personnel in molecular testing companies: previous

experience in communicating with patients about molecular testing related to lung cancer targeted therapy; (4) for nurses, hospital administrators and personnel in insurance companies: understand the decision-making process.

Exclusion criteria for other stakeholders

There is one exclusion criterion: inability to understand the research content.

Withdrawal criteria for patients

Withdrawal criteria for patients are as follows: (1) the participant is unable to participate in the interview or cooperate in completing the study due to serious postoperative complications; (2) the participant does not cooperate with the structured interview according to the research programme interview outline; (3) the participant cannot clearly express their views during the interview; (4) the participant does not follow the study plan; (5) the participant asks to withdraw from the study and (6) the investigator identifies other situations that required withdrawal from the study.

Withdrawal criteria for other stakeholders

Withdrawal criteria for other stakeholders are as follows: (1) The participant fails to cooperate with the semistructured interview according to the interview outline of the research plan; (2) the participant is unable to express their views clearly during the interview; (3) the participant does not comply with the study plan; (4) the participant asks to withdraw from the study and (5) the investigator identifies other situations that required withdrawal from the study.

Data analysis

The participants' demographic data and answers to the interview questions will be audiorecorded but not transcribed verbatim. After completion of each round of interviews, audiorecordings will be reviewed by the investigators to identify any problems in the content of the DA_LCMT 1.0. Problems will be summarised in a tabular format. The expert panel will discuss the problem, deliberate on the problem item, revise the content accordingly and further test it with the next group of participants. The entire cognitive debriefing process will be performed through several rounds of interviews with different participants until no substantial changes are observed.

Field testing (beta test)

The purpose of the beta test is to examine the usability of the DA_LCMT 2.0 in a real-world setting though one to one qualitative structured interviews.[37]

Inclusion criteria for patients

Inclusion criteria are as follows: (1) age ≥18 years; (2) patients with primary invasive adenocarcinoma of lung diagnosed by intraoperative frozen pathological section and (3) has not decided whether to perform lung cancer molecular testing.

Exclusion criteria for patients

There is one exclusion criterion: inability to understand the research content.

Inclusion criteria for other stakeholders

Inclusion criteria are as follows: (1) age ≥18 years; (2) relevant work experience ≥2 years; (3) previous experience in communicating with patients about molecular testing related to lung cancer targeted therapy and (4) voluntarily participates in this study.

Exclusion criteria for other stakeholders

There is one exclusion criterion: inability to understand the research content.

Withdrawal criteria for patients

Withdrawal criteria are as follows: (1) the final postoperative paraffin pathological section diagnosis is non-primary lung adenocarcinoma, adenocarcinoma in situ (AIS) or AIS with microinvasion; (2) due to serious postoperative complications they cannot cooperate in completing the study; (3) the participant does not comply with the study plan; (4) the participant asks to withdraw from the study and (5) the investigator identifies other situations that required withdrawal from the study.

Withdrawal criteria for clinicians

Withdrawal criteria are as follows: (1) cannot use DA to assist in SDM; (2) unable to make shared decisions with patients; (3) failure to comply with the study plan; (4) the participant asks to withdraw from the study and (5) other situations that the investigator identifies as necessary for withdrawal from the study.

Data analysis

The participants' demographic data will be collected and audiorecordings will be reviewed and discussed by the expert panel for iterative improvement and revision of the DA_LCMT 2.0; saturation will be reached if the last three beta tests did not lead to substantial changes to the DA_LCMT 2.0.

Data collection, management and monitoring

The REDCap data platform will be used for data management in this study.[41 42] All study data, except interview audiorecordings, will be stored in REDCap, and the interview audiorecordings will be summarised and kept in separate, confidential files and password protected to ensure data security. The REDCap system has been installed directly on the server of the Sichuan Cancer Hospital and Institute. Each database is managed by the researcher or a designated person, to ensure data security. Except for audio interview recordings, all data will be entered into the REDCap data platform by data entry personnel. The data will receive two types of checking by quality control personnel—double checking of the entire database and random checking of 10% of the data.

Quality control

Investigators will receive training on standard operating procedures prior to each section of this study. Investigators in all research centres will receive regular online or on-site guidance, monitoring and supervision by the principal investigator and international experts. The audio recordings of the interviews will be checked regularly to ensure that the method and content of the interviews are carried out in strict accordance with the research protocol. Interviews deviating from the research plan will be fed back to the corresponding researcher to ensure that they can be improved in the following study and meet the research requirements.

Data analysis

All data ultimately included in the analysis will meet the inclusion criteria and will not meet the exclusion and withdrawal criteria. Continuous variables with a normal distribution will be presented as mean±SD or as median and IQR. Categorical variables will be presented as numbers, percentages or proportions. The qualitative data will be analysed using the qualitative software NVivo V.12 (QSR International. 2020. http://www.qsrinternational.com). Other non-qualitative data analyses will be performed using Statistical Analysis System (V.9.4).

Patient and public involvement

Patients or the public will be involved in the design and dissemination plans of our research, but will not be involved in conducting it and reporting the findings. Patients and the public will participate in the development of the interview outline before each part of the study and will be encouraged to invite others to join the study. Patients will not be informed of the results of the study unless they request it at the time of enrolment. However, the results of the study will be distributed to the applicants in the form of published articles, as required, and used in subsequent studies.

ETHICS AND DISSEMINATION

Ethics Committee for Medical Research and New Medical Technology of Sichuan Cancer Hospital approved this study on 21 December 2021 (No. SCCHEC-02-2021-105). The study was also approved by the Ethics Committees of The Third People's Hospital of Chengdu, Zigong First People's Hospital, and Jiangyou People's Hospital. All participants will provide informed consent. The results of this study will first be reported at academic conferences and will eventually be published in peer-reviewed journals.

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Contributors Study conception and design: XW, YL, WD and QS. Drafting of the abstract: XW, QS. Critical revision of the article for important intellectual content: XW, YL, HY, WD, DY, KZ, JS, WX, RG, QY, YP, YW, JL, YM, YZ, WF, QP, QL and QS. Final approval of the version to be published: XW, YL, HY, WD, DY, KZ, JS, WX, RG, QY, YP, YW, JL, YM, YZ, WF, QP, QL and QS. Funding acquisition: XW and QL. Administrative, technical or material support: HY, QL and QS.

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Competing interests None declared.

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