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Qualitative study of oncologists' perceptions on the US Food and Drug Administration approval status and clinical practice guidelines and their impact on local practice patterns in India

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ABSTRACT

Objective How the US Food and Drug Administration (FDA) approval status and international cancer care guidelines influence the practice of oncology in low-and-middle-income countries like India has not been studied so far. We aimed to study how oncologists in India perceive drug approval status and guideline recommendations for their own clinical practice.

Methods and analysis The study followed qualitative research design, incorporating semistructured interviews. The participants were qualified medical oncologists in India representing a wide range of geographical regions, including East, West, North and Southern India. Data were collected using a semistructured interview schedule. In-depth qualitative interviews were undertaken, and all interviews were transcribed verbatim. Data analysis followed the principles of thematic analysis to generate themes.

Results Of the 25 medical oncologists interviewed for this study, 15 (60%) showed awareness of the limitations of the US FDA approval, including those of accelerated approval and approvals based on phase 2 trials. They also expressed disappointment about the lack of availability and affordability of cancer drugs and wished for more representation of Indian patients in the pivotal trials leading to the US FDA approval. NCCN guidelines were the most used guidelines and participants showed strong support for local institutional guidelines. However, participants felt that resource-stratified guidelines from different societies were not very helpful.

Conclusions Oncologists in India demonstrated awareness of the limitations of the US FDA drug approvals and found resource-stratified guidelines to be unhelpful. They preferred the main guidelines and institutional protocols over resource-stratified guidelines.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is not much in the literature about how medical oncologists in low-and-middle-income countries (LMIC) like India make treatment decisions. In a previous study, we explored how clinical trial designs, magnitude of clinical benefit and price of drugs affect these decisions.

WHAT THIS STUDY ADDS

⇒ This study adds to that evidence base by providing results on how the US Food and Drug Administration (FDA) approval status and inclusion in cancer treatment guidelines affect treatment decisions of Indian oncologists. It also explores their opinions about the US FDA approval process, international cancer treatment guidelines, resource-stratified guidelines, national and institutional guidelines, as well as personal choices in making treatment decisions.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our study suggests that the US FDA approval status affects Indian oncologists' practice, but they are also concerned about the low approval standards. We also find that Indian oncologists usually do not refer to resource-stratified guidelines but consult the main guidelines. These results encourage regulators and guideline-makers to consider applicability in the Indian and other LMIC contexts.

INTRODUCTION

Cancer drugs constitute the majority of new drug approvals[1] as well as a substantial percentage of cancer care expenditure.[2] Because of the rapidly evolving science, several new cancer drugs are tested, trialled, approved and moved into guidelines every year, changing the standard of care. Although the practice of medical oncology in high-income countries is more standardised in that they are dictated by drug approvals, reimbursements and clinical practice guidelines, the same is not necessarily true in low-and-middle-income countries (LMICs).[3] In many LMICs, the regulators are not as timely or efficient.[4] Furthermore, in many situations, patients pay from pocket for their treatment.[5]

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In the absence of efficient approvals or public funding schemes, the treatment approach will not be dictated by what is approved or what is best, but rather by what is available and affordable. Many LMICs also lack treatment guidelines adapted to their settings. On the other hand, because treatment choices are based on what is available and affordable, some patients who can afford new therapies can also be potentially overtreated with marginally beneficial drugs. Thus, how oncologists make treatment decisions in LMICs is complex, multifactorial and worthy of detailed investigation.

Our team has previously studied the perceptions of Indian oncologists surrounding surrogate endpoints, overall survival (OS), magnitude of benefit and price of cancer drugs.[6] However, in addition to clinical trials data and prices, oncologists' practice patterns in LMICs like India can also be influenced by approval status of the drug by national and international regulators, inclusion in treatment guidelines and local practice patterns. In India, where the study was conducted, Central Drugs Standard Control Organization regulates the quality of medications marketed in India under the Drugs and Cosmetics Act, 1940 and Rules thereunder. However, the practice patterns may also be influenced by the US Food and Drug Administration (FDA) because the US FDA approval status is heralded as a benchmark of quality and the FDA approval of a new cancer drug is heavily promoted by the industry in India.[7] In addition, several international societies such as the American Society of Clinical Oncology (ASCO), European Society for Medical Oncology (ESMO) and National Comprehensive Cancer Network (NCCN) also now publish resource-stratified guidelines (RSG) meant to be used in LMICs like India. However, whether oncologists on the ground in India actually use these RSG has been understudied.

In this current study, we aimed to study the perceptions of Indian oncologists about the roles of the US FDA approval status, international and national cancer treatment guidelines including RSG and local institutional practice patterns on their own practice.

METHODS

The study received approval by the ethics committee (2020/TMC/174/IRB4) of Tata Medical Center, Kolkata. This study is a follow-up study to our previously published study, which studied Indian oncologists' perceptions regarding surrogate endpoints, magnitude of benefit and drug prices.[6] The methodological orientation followed in the study was content analysis.

The current manuscript reports on the results of the qualitative in-depth interviews of medical oncologists in India on their perceptions of the role of the following factors on their drug prescription practice: (1) the US FDA approval status; (2) international guidelines such as NCCN, ASCO and ESMO; (3) RSG; (4) national guidelines; and (5) local practice patterns. The roles of OS, progression-free survival (PFS), magnitude of benefit and price of drugs have already been published.[6] The US FDA was chosen as the representative international regulator for its global reputation, including being the first regulator to approve most cancer drugs before other regulators,[8] as well as the impact of its approval decisions on Indian practice.[7]

The study adhered to the Consolidated Criteria for Reporting Qualitative Research guideline for reporting qualitative research.[9] Medical oncology consultants in India with more than 2 years of experience in prescribing drug therapy for patients with early and advanced solid cancers were invited to participate in the study. Participants were recruited using a purposive sampling method to ensure representation from oncologists of different experience levels, geographies, hospital settings (public, private, both) and genders. Participants were contacted by email or a phone call, and the researchers ensured that participation was voluntary, and written informed consent was obtained from each participant before the interview. All interviews were conducted in English, and every participant was interviewed only once.

Data collection

Qualitative data were collected through in-depth interviews, either face-to-face or virtually using Zoom software. It was ensured that the participants were in a private office space, free from distractions. Participants could withdraw participation at any time before, during or after the interview. All participants participated in a single interview, and transcripts were not shared with the participants. To prevent any bias from the fear of being judged, all interviews were conducted by SSD and AM, who are psycho-oncologists who do not prescribe cancer drugs themselves, and did not have any prior relationship with the study participants. In-depth qualitative interviews were conducted by two researchers (SSD and AM), both of whom are trained in qualitative interviewing methods. The interviews were conducted online or face-to-face at a time that was convenient for the respondent. To maintain focus, the interviews were semistructured, and specific questions developed by the research team, which included oncologists with experience practising in India, were used (online supplemental file 1). The interviewers made concurrent field notes to record observations of verbal and non-verbal reactions during each interview. A semistructured interview in qualitative research combines a flexible interview guide of predetermined open-ended questions with the freedom to explore emergent topics and get in-depth insight into what emerges during the interview. We chose this method of interviewing because we were exploring decision-making in oncology, which involves multiple factors that influence the decisions made by both oncologists and patients. The questions and interview guides were piloted with the first five oncologists, and the interview was modified to ensure the questions were understandable to the respondents. For many of the questions, the participants were encouraged to articulate their perspectives in an open-ended conversational manner. There was also an option for discussing any related topic that they felt was important. The entire interview, including the interviewer's reactions, was recorded and transcribed to understand the context of the discussion. Subsequent interviews explored any area that came up in the previous interview until data saturation was reached. Data collection was stopped once data saturation was reached, and further interviews no longer contributed new information. Data saturation can only be judged if data collection and data analysis are conducted side by side. The idea of theoretical saturation, first suggested by Glaser and Strauss,[10] is described as a process in which the researcher can continue to interview and analyse the qualitative data until no new theoretical insights are generated from the data. We followed the same approach in our study. All interviews were audio-recorded, and verbatim transcripts were created for analysis. Transcriptions and data were stored securely at Tata Medical Centre, Kolkata. Field notes were maintained by the researcher during each interview.

Data analysis

Data collection and data analysis were conducted concurrently to explore further details of the themes generated in subsequent interviews. All transcripts were anonymised and subsequently coded manually by two independent researchers (SSD and VS) in the team using the principles of thematic analysis. Coding in thematic analysis entails labelling and categorisation of qualitative data, such as interview transcripts, to uncover recurrent patterns and emergent themes. The codes were reviewed by a third senior researcher (BG), who sorted out any discrepancies between the two coders. The qualitative data analysis process comprised the following steps: (a) generating initial codes guided by the principles of thematic analysis, (b) charting the data, (c) synthesising the data, (d) formulating basic themes and (e) developing global themes. The identification of basic and global themes followed the approach to thematic analysis outlined by Braun and Clarke.[5] In thematic analysis, 'basic themes' represent foundational patterns or ideas identified in the data. In contrast, 'global themes' are overarching concepts that integrate and give meaning to clusters of related basic themes. Quantitative data were analysed using simple descriptive statistics.

Patient and public involvement

Patient and Public were not involved in the design and conduct of this study because this was a study on physician participants. However, patients and the public are part of the dissemination plan. We work closely with patient advocates and media in India, and we plan to disseminate the results of this study both with media at the time of publication and patients and public during our annual ecancer meeting in India, which is attended by patients and public in large numbers.

RESULTS

Of the 30 oncologists who received invitations, 25 accepted to participate and were interviewed (76% males, median age 40 and 10 years of work experience as a medical oncologist) for a mean duration of 35 min, and a median of 18 min (range, 6.2 to 47.0 min) (online supplemental table).

Perceptions regarding the role of the US FDA approval status

Participants highlighted the role of US FDA approval status for the scientific trust, but major concerns also emerged that concentrated on two major themes: lack of applicability to Indian practice and the approval standards at the US FDA (table 1). Overall, 15 oncologists (60%) expressed awareness of the limitations of the US FDA approval status for cancer drugs. Participants expressed that the US FDA approval status would give them confidence about the safety of the product, but they would not necessarily follow the FDA approval because of the small magnitude of benefit of certain cancer drugs. Several oncologists raised concerns specifically related to accelerated approvals and approvals based on phase 2 trials. However, no participant discussed the withdrawal of approvals. Some participants also raised concerns with approval standards beyond accelerated approval.

Specific concerns also emerged surrounding the (lack of) applicability of the US FDA approval to Indian practice: first, the lack of representation of local patient population in the pivotal trials leading to the US FDA approval and second, the lack of availability or affordability of the drug in India. Interestingly, a couple of participants also brought the issue of doses–especially with immunotherapy–where they mentioned that the dose recommended in the FDA labels was far higher than the dose they used in clinical practice.

Perceptions regarding international cancer care guidelines

NCCN guidelines were the most commonly used guidelines (76%), followed by ESMO (60%) and ASCO (28%) guidelines (table 2). 16% oncologists mentioned referring to national and local institutional guidelines, each. Among those who used the international guidelines, most used the main guidelines and not the resource-stratified versions.

During the in-depth interview, participants highlighted the need to customise the international guidelines to local needs and situations (table 3). However, participants did not prefer the RSG, because they were not thorough and assumed that resources were similar across LMICs, or across different patients within the same LMIC. For example, one participant mentioned, 'I look at both (main and resource-stratified) because there is a subset of patients in our country who cannot afford everything. And then there is another group of patients where it would be wrong just to use resource-stratified guidelines'. Similar to this participant, a few oncologists (16%) mentioned they had use both main guidelines and the resource-stratified version.

Table 1 Summary of qualitative themes for drug approval status

Qualitative themes	Examples
The FDA approval status is important	
Trust in the scientific process	*Yes… I give importance to that (FDA approval status)…I will say most of the time…when a drug is concerned, I will go by FDA-approved drugs. (P2*) *Certainly, I value FDA guidelines firstly because it is an authentic regulatory body and secondly, its approval is generally based on scientific studies. (P5*) *Without FDA approval or DCGI approval, we can't prescribe any drug unless it is a very personalised therapy the patient is receiving, for example, fourth, fifth or sixth-line therapy for which there is no FDA approval. There, we can discuss case by case, and then take a call. But practically, this happens in less than 5% of cases where we prescribe a drug that is not pre-approved. Otherwise, in 90 to nearly 100% of cases, we consider the FDA approval status. (P14*) *There is no other thing to rely on". (P15*)
The FDA approval is important, but caution is needed	
The FDA does not take magnitude of benefit into account	*However, some drugs have received FDA approval despite showing only a 2- or 3-day or 7-day survival benefit. So, we must take those approvals with a pinch of salt. We need to be rational rather than following the FDA approval status blindly. (P1*) *I must eventually rely on the FDA approval. However, the FDA, at times, had approved treatments that offered a PFS benefit of only 15–20 days, and the cost was substantial. In those cases, I may not use it. (P15*)
For medico-legal and safety reasons	*FDA approval status is primarily intended to ensure medical-legal safety and to prescribe the correct drug at the appropriate dose. (P1*) *I don't blindly follow FDA approval. Suppose there is no FDA approval, I am more cautious and sceptical about using that drug because it has not received approval yet, for that indication. But suppose the drug got approval by the FDA, I have my own yardstick. (P19*)
Concerns with approval standards	
Concerns with accelerated approval	*Definitely, FDA approval adds a little more confidence. However, as an oncologist, I am concerned about the accelerated approval process. There have been many instances in the recent past where the conditional approval has been granted and later the confirmatory trial has failed to replicate the result, and then this approval has been taken away. (P7*) *There is a term—'accelerated approval'—that has come up in the last few years. We have seen many drugs that got approval (initially), and after longer-term follow-up, when the outcome data came out or the data matured, then approval was withdrawn. So, in fact, the healthy practice is to indulge in academic discussions, participate in CMEs, discuss among your peer group, get into the details of that trial, and only then decide. It's not just blind faith in FDA approval. (P19*) *I think FDA approval status is important. But accelerated FDA approval status based on Phase II studies is something which I don't give importance to, especially in my clinical practice. (P23*) *I think FDA approval is a very strict approval in most cases. However, we have accelerated approvals given for certain indications, often for the immunotherapeutic agents. Mostly, accelerated approvals are given by the FDA based on minimal amounts of Phase II study data. I would take those with a pinch of salt. But in others, if it's based on a phase three trial, which is proven, given in a proper setting, those are acceptable. (P20*)
Concerns with the FDA approval in general	*I would not give FDA approval a very high weightage because the FDA approval is given even for the minimal benefit, and the drugs can be very expensive. (P12*) *I give no importance to the FDA approval. I have discussed this in numerous meetings. They have significantly lowered their standards, particularly in accepting the Pathological Complete Response as an endpoint. I still find the EMA (European Medicines Agency) is a bit robust. But the FDA has really lowered its standards for the last couple of decades, I think. (P6*)
More trust on trials than the FDA	*We don't give importance to it (FDA approval). I think everything boils down to the study that is published," (P8*) *"Practically speaking, nobody cares about the FDA approval. For us, it is the patient and availability. These are the two things that matter. Therefore, if the data is available, which is convincing to us, then it should certainly be provided to the patient. And that is how the whole philosophy of medicine goes on. (P13*)
The FDA approval does not apply to India	
Because the FDA approval data do not include Indian patients	*"…most of the FDA approvals are given based on studies conducted worldwide. Most of the trials have not been a good representation of the Asian population to assess the response in the Asian ethnic population. So, for that reason, I take it with a pinch of salt." (P20*) *"I don't give much importance to the FDA approval status for the drugs because our patient population is entirely different from the patients participating in clinical trials done in the West." (P18*)
Because the drug is unavailable or unaffordable despite the FDA approval	*"Though the FDA approval may be given, it may take a minimum lag period of 4–5 years and sometimes more to get the DCGI approval…… After FDA approval, 90% of the time, either the product is not available or it is too costly, and thus no one has access to it. So, it doesn't (matter) much till there is scientific evidence to support the use of the drug." (P4*)

Continued

Table 1 Continued

Qualitative themes	Examples
There is no reason to follow the FDA approval status for India	*"I am aware of what is FDA-approved and what is not approved. I am also aware of the limitations of that approval. But because the FDA has not approved a medication, it does not stop me from using it in India." (P21).* *"In the country of practice that is India, we do not give much importance to the US FDA. We use it as a baseline and benchmark. We generally like to see whether our own approval body, that is the DCGI, has given the approval for that drug for that particular cancer" (P10)*
Issues about doses	*"We do take the FDA approval into account. But in our institution, most often we are not able to use the dose that is recommended by the FDA, especially for immunotherapy drugs. So, we do something called "low dose immunotherapy" for specific malignancies like head and neck lung cancers, hepatocellular carcinoma and renal cell carcinoma. We have some encouraging data from our centre, as well as from Mumbai and Korea. So, we routinely use that, but we also tell the patient that what we are doing is less than the FDA-approved doses. And it's our own institutional practice that has led to recommending the drug, and it is not an internationally approved approach." (P22)*

CME, Continuing Medical Education; DCGI, Drugs Controller General of India; FDA, Food and Drug Administration; PFS, progression-free survival.

Perceptions regarding national cancer care guidelines

When asked about their perception of the role of national cancer care guidelines, participants acknowledged the importance but lamented the lack of such national guidelines for different cancers (table 4). One participant mentioned, 'protocol-based management of cancer is very important. But in India, we do not have many approved or well-established guidelines. So, we follow the current scientific data as well as the guidelines by important scientific bodies in oncology'. Some participants also raised concerns about national guidelines because of biases and conflicts among the guideline experts ('it is all up in the air, except very few exceptions when they (experts) don't bring in their biases. But at times they can be so full of conflict of interest and bias that we do not read the document at all') or because of high cost of some treatments included in the guidelines ('many patients won't be able to afford those types of therapies').

Table 2 Cancer Care Guidelines most often used by Indian oncologists

Guidelines	Frequency	Percentage
American Society of Clinical Oncology Guidelines	7	28%
European Society for Medical Oncology Guidelines	15	60%
National Comprehensive Cancer Network Guidelines	19	76%
Royal College of Radiology Guidelines	1	4%
National Institute for Health and Care Excellence Guidelines	2	8%
National Guidelines	4	16%
Institutional Guidelines	4	16%
Preference for Main vs Resource-Stratified Guidelines wherever applicable		
Main Guidelines	15	60%
Both Main and Resource-stratified guidelines	4	16%
Neither Main nor Resource-Stratified guidelines	4	16%

Many respondents chose more than one choice.

Perceptions regarding local institutional protocols

In contrast, 40% participants expressed strong support for following local institutional treatment protocols ('I am very particular about institutional protocols. Whatever cancers I deal with and whatever departments I work in, we make sure that we develop our own set of protocols, and we stick to it for the most part') (table 5). Participants expressed the need to timely update the institutional protocols ('it would be nice to review them every 6 months or 12 months') and ensure consensus among the oncologists ('Institutional protocol shouldn't be a one man show, it should be a uniform decision among the treating people').

Perceptions regarding physicians' personal choice in making treatment decisions

Physicians made it clear that treatment choices should be based on evidence rather than personal preferences ('There should not be treatment based on personal choice. It should always be based on high-level evidence and institutional protocols'). However, some physicians agreed that when there are no guideline-recommended options (such as when treatment options are exhausted) or if the patient is paying from their pocket, then treatment based on physicians' choice can be considered (table 5).

DISCUSSION

This in-depth qualitative study of Indian oncologists provides an understanding of how the FDA approval status, international, national and local guidelines, and personal choices influence cancer treatment decisions

Table 3 Summary of qualitative themes for the role of international guidelines

Qualitative themes	Examples
International guidelines are important, but need to be customised	
There will always be variation between international protocols, national and local guidelines. This is true because of the variation in incidence, prevalence, drug sensitivity, socioeconomic background, genetic background and many other factors that make the outcome different in different settings. We have to accept this, and as per the local institutional, geographical or demographic variation, we have to modify our treatment. (P4) *We don't blindly follow NCCN, we don't blindly follow NICE guidelines. We try to adapt those guidelines to our local practice. Here I am talking about polymorphisms and body surface area, which is so different from fat percentage and nutritional issues. I am also talking about local issues like infections that occur in India that don't occur abroad. Then, planning the very heavy chemo protocols in these patients can be a challenge. (P7)*	
Concerns with resource-stratified guidelines	
Main guidelines are more thorough	*I usually use the main guidelines, as you would like to know what the treatment options are that we can discuss with the patient, and also for treatment planning. (P1)* *We use the main guidelines. (P2)*
Resource-stratified guidelines are diluted versions of main guidelines	*Resource stratified guidelines just blank out some choices mentioned in the main guidelines. (P1)* *I use the comprehensive main guidelines to read. (P13).*
They are not adapted to LMICs well	*Unfortunately, the guidelines are least bothered about the lower- and middle-income countries. I guess resource stratification, or any modification, is based upon the resources. They assume that resources are the same everywhere. (P10)*
In Support of resource-stratified guidelines	
Not instead of, but in addition to, the main guidelines	*Mainly the main guideline, but recently I started seeing the resource-stratified ones also. (P1)* *I look at both because there is a subset of patients in our country who cannot afford everything. And then there is another group of patients where 'it would be wrong just to use resource-stratified guidelines'. (P7)*

LMIC, low-and-middle-income countries; NCCN, National Comprehensive Cancer Network; NICE, National Institute for Health and Care Excellence.

in India. These insights also offer important opportunities for intervention in terms of how these treatment decisions can be improved, and policy lessons on what works and what does not work on the ground in LMICs like India.

Although the US FDA approval status has a legal holding only in the USA, it is looked on globally as a surrogate for quality of evidence and trust in the medicine.[11] Our study confirms that perception, however, participants seemed to be very aware of the limitations of the FDA approval. Participants raised important concerns such as the lack of representation of Indian population in the pivotal trials. A previous analysis from the US FDA has shown that the enrolment of Asian patients within the USA was <1%, and Indian patients constituted <0.7% of all enrolled patients among the registration trials for major cancers.[12] It would be important to improve the representation of Indian Americans and patients from India in future registration trials to make the results more generalisable. However, participants were also concerned about the lack of access to drugs despite the US FDA approval. This is also consistent with the concerning recent trend of globalisation of cancer drug trials where the trials are conducted in LMICs with an inferior control arm, just to get the drug approved in the USA.[13 14] A previous study has shown that for registration trials where Africa has participated, zero per cent of the drugs were available in Africa 5 years after the drug's approval by the US FDA.[15] As the US FDA is planning a more intricate relationship with India through Project ASHA, these findings should be considered in policymaking.[16]

Indian oncologists showed awareness of the limitations of accelerated approval as well as approvals based on a phase 2 trial. Indeed, in recent years, several papers have highlighted the limitations of accelerated approval and ways to improve the process.[17–20] Another interesting highlight of our study was the omission of any discussion from any participant regarding withdrawal of accelerated approval by the US FDA. Previously, we have discussed how a drug approved by the US FDA is promoted in India, while the withdrawal of the same drug by the U.S. FDA is attempted to be swept under the blanket.[7] This may be an area for a separate future research study.

Some participants brought up an important issue of why the US FDA-approved dose may not be the most cost-effective dose. Indeed, in recent years, studies have shed light on how several drugs may be given at a lower dose or frequency or duration than that approved by the US FDA.[21] One participant specifically mentioned the use of ultra-low-dose immunotherapy in their practice, which is 1/20th the dose recommended by the US FDA. This was indeed supported by a trial conducted in India.[22] There

Table 4 Summary of qualitative themes for the role of national and local guidelines

Qualitative themes	Examples
National guidelines	
Lack of national guidelines	*Protocol-based management of cancer is very important. But in India, we do not have many approved or well-established guidelines. So, we follow the current scientific data as well as the guidelines by important scientific bodies in oncology, like ASCO, ESMO and NCCN. We read these, use our minds and we use them in a customised manner. We do not follow them blindly.* (P3) *If we are part of a study, we must follow a national protocol. But otherwise, I don't think there are many national protocols. Recently, there have been some efforts, like the NCG, that have come out with guidelines that I was part of. Some of those are useful. But I don't think in our department we follow those.* (P11) *We in India are now working on developing our own guidelines, the ICMR, our own ISMPO, and a national cancer grid. Practically, we still rely on the Western NCCN and ESMO guidelines.* (P15)
Concerns with national guidelines	*National protocols: it is all up in the air, except for very few exceptions when they (experts) don't bring in their biases. But at times, they can be so full of conflict of interest and bias that we do not read the document at all.* (P8) *I don't generally follow national protocols as these are very vague, and they are a bit theoretical. Many patients won't be able to afford those types of therapies.* (P1) *I do not give importance to DCGI approvals because I think they are very laid back in giving approvals. And the requirements for DCGI approval are sometimes not up to the mark*.
Institutional protocols	
Strong support for institutional protocols	*I am very particular about institutional protocols. Regardless of the cancers we deal with and the departments we work in, we ensure that we develop our own set of protocols and adhere to them for the most part. And we periodically review it so that we do change according to whatever is new.* (P11) *For most of the organ sites I practise, there are institutional protocols. These institutional protocols are based on international guidelines according to the evidence base and their applicability to our centre, which is crucial. Hence, I give a lot of importance to institutional protocols that are based on the international guidelines and evidence-based.* (P2) *I give a lot of importance to prescribing practice locally. So, I mean, thinking global but acting local is very, very important. My preference would be institutional protocols.* (P8)
Lack of institutional protocols	*Most institutes, unlike Tata Hospital, don't have their own protocols.* (P7)
Robustness and timely update of institutional protocols is important	*Institutional protocol shouldn't be a one-man show; it should be a consensus among the clinicians. So, if that is the way the institutional protocol is made, I have no problem.* (P1) *We must rigorously look at how things are going. And honestly, it would be nice to review them every 6 months or a year. We are in the process of making it real-time. So, every 6 months you review and then, you know if you must make any changes and you do it.* (P8) *For our institute, we have a regular meeting every 2 years. Recently, we developed our own institutional protocols and, by and large, around 80%–90% of the time, we adhere to those protocols. When we move on, there is a consensus of around 15 medical oncologists. However, things are changing so rapidly; every 3 months, something new emerges. So, it is sometimes very difficult to follow one protocol.* (P13)
Opposition to institutional protocols	*I don't give that much importance to local prescribing patterns because that's not the standard of care which you should follow. We should follow the guidelines.* (P20)

ASCO, American Society of Clinical Oncology; DCGI, Drugs Controller General of India; ESMO, European Society for Medical Oncology; ICMR, Indian Council of Medical Research; ISMPO, Indian Society of Medical and Pediatric Oncology; NCCN, National Comprehensive Cancer Network; NCG, National Cancer Grid.

are other opportunities for dose optimisation, such as consuming abiraterone with a low-fat meal[23] or lapatinib with food and grapefruit juice.[24] These interventions help reduce financial burden while maintaining clinical benefit. Even in situations where data are supported by evidence, such as reducing the frequency of zoledronic acid or the duration of adjuvant therapy for oxaliplatin in colon cancer or the duration of trastuzumab in breast cancer, FDA labels are not regularly updated,[25] and thus, Indian oncologists are correct in not relying on the FDA labels for the dose of the medications they use. Another approach to reduce financial burden would be to legalise and implement the redispensing of unused oral anticancer drugs with quality assurance protocols.[26]

Our survey has also uncovered some crucial insights regarding the use of clinical practice guidelines in India. Oncologists most commonly used international guidelines but also expressed strong support for local institutional

Table 5 Summary of qualitative themes for personal choice in making treatment decisions

Qualitative themes	Examples
Treatments should not be based on personal choices	
Personal choices should be the last thing on your mind while treating malignancies. (P10) *Personal choice (in choosing treatment options), I do not agree to. There should not be treatment based on personal choice. It should always be based on high-level evidence and institutional protocols. (P9)*	
Personal choice has a role	
When there are no guidelines	*Personal choice is reserved mainly for second or third line of treatment or treatment of recurrent disease where there are no clear-cut guidelines. (P1)*
When paying out of pocket	*When the treatment cost comes from out-of-pocket expenses, then the question of personal choice is there. I would explain all the benefits. But if something comes from an insurance or the government is giving the money, then I would look at an institutional protocol or a national protocol. (P12)*

treatment protocols, as long as they were based on consensus and regularly updated. However, they were not as enthusiastic about national guidelines. They expressed concerns about potential biases of guideline members, despite acknowledging that more national guidelines were needed. Since guideline development is a resource-intensive undertaking, one pragmatic approach that has been suggested in the past was to adapt guidelines developed elsewhere for India.[27] As the National Cancer Grid in India establishes and adds more guidelines,[28] it would be important to consider these recommendations from Indian oncologists and repeat such a study a few years later to assess if their perceptions have changed.

Probably the most insightful and surprising finding from our analysis was the lack of enthusiasm for RSG in the real world in India. This was surprising because we believed, similar to many others, that RSG offered value to clinicians in LMICs.[29] Several international oncology societies and institutions have spent considerable money, time, manpower and resources to build RSG with the hope that they would be useful to colleagues practising oncology in LMICs. Our study questions the utility of these RSG. Most participants in our study preferred referring to the main guidelines, rather than the resource-stratified versions. They preferred tailoring to their context by themselves, since all resource-limited settings are different and even within the same setting, the treatment choices for a rich patient would be different from that for a poor patient. Participants also thought that RSG were not as scientific as the main guidelines. These concerns are consistent with a viewpoint previously expressed by another LMIC oncologist from Nepal.[30] Indeed, even among the RSGs, there is substantial discordance.[31] Studies involving physicians from other LMICs are needed to understand whether this is an India-specific finding or remains true for other LMICs as well. Societies and institutions should run similar pilot tests to understand the utility and uptake of their RSG (or other interventions) before dedicating their resources to this, because we believe this has an opportunity cost. For instance, the resources used to develop RSG for a cancer from one international oncology society would probably fund a de-escalation patient-centric trial in a LMIC. In addition, most clinical guidelines are also based on clinical trials that are conducted in HICs with sparse representation of patients from LMICs, and thus results may not routinely apply to patients in LMICs who receive different post-protocol treatments, supportive care and survivorship care.[32 33]This inequity in generation, production, use and circulation of knowledge necessary for treatment of patients with cancer contributes to epistemic injustice in global oncology.[34]

Together with our previous work,[6] this study provides an understanding of how oncologists make treatment decisions in India. Taken together, we have now shown how oncologists in India consider the role of price of cancer drugs, magnitude of benefit, choice of endpoint, as well as the US FDA approval status, international, national and local cancer care guidelines, and personal choices in making treatment decisions. More recently, government-funded insurance programmes in India cover several cancer drugs, and this can also affect oncologists' treatment choices.[35] However, this conversation did not appear during our interviews and should probably be studied separately in the future.

Several caveats should be considered in interpreting our study. Although the sample size is relatively small, there was saturation in themes, and therefore, we considered the sample to be adequate, especially for a single-nation study. There always remains a possibility of self-selection bias in such studies. Since these interviews take some time (mean duration was 35 min), the participants who agree to be interviewed are usually interested in these topics, and hence, their answers may not be reflective of others who did not accept to participate. However, we did receive diverging opinions. In addition, our sample has overrepresentation of males (76%), but this reflects the gender balance in the actual oncology workforce in India.[36] Importantly, our results are reflective of Indian practice which may not be generalisable to other LMICs. However, given the comparability of health systems, our results probably apply to other LMICs within the South Asian Association for Regional Cooperation region.[37 38]

In summary, our study shows that oncologists in LMICs such as India are aware of the pitfalls and limitations of the US FDA approval as well as resource stratified guidelines from international societies and tailor the practice based on local needs, affordability and evidence. They also value local institutional guidelines based on evidence. These results signify the global importance and implications of FDA approval status and highlight the need to study the relevance of RSG before investing even more into their development. Our results also underscore the importance of developing evidence-based and transparent national and local institutional guidelines. The results herein provide important information for regulators and policymakers regarding clinical trial generalisability, drug approval processes and use of guidelines in resource-limited settings.

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