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A novel evidence-based multilevel model of stigma and barriers to cancer palliative care in India generated from qualitative in-depth interviews.

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A novel evidence-based multilevel model of stigma and barriers to cancer palliative

care in India generated from qualitative in-depth interviews

Richard Harding (corresponding author)

Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care

King's College London

Cicely Saunders Institute

Department of Palliative Care, Policy & Rehabilitation

Bessemer Road

London, UK

SE5 9PJ

Email: richard.harding@kcl.ac.uk

Tel: +44 (0) 207 848 5518

Shoba Nair

Department of Pain and Palliative Medicine

St John's Medical College Hospital

St John's National Academy of Health Sciences

Bengaluru, India

Maria L Ekstrand

Division of Prevention Science

Department of Medicine

University of California, San Francisco, USA

and

St John's Research Institute

St John's National Academy of Health Sciences

Bengaluru, India

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Abstract

Introduction Palliative care coverage and opioid consumption in India are relatively low compared to global data. The literature suggests commonplace concealment and collusion in withholding information, but these hypotheses lack evidence.

Objectives This study aimed to develop a plausible evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

Design This cross-sectional qualitative study sampled advanced cancer patients (n=10), their family caregivers (n=10), and oncologists (n=10). Grounded theory procedures were utilised to analyse transcripts, and a theoretical model generated.

Setting A tertiary teaching hospital in South India.

Results The model explains how stigma associated with communicating a diagnosis of advanced cancer is enacted by treating oncologists, family members and community. This leads to patient expectations of cure and futile treatment uptake. Patients only present needs with respect to pain and none within psychological, social or spiritual domains, likely due to the lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack of insight, palliative care clinicians view their services as underutilised, and patients perceive palliative care as a pain management service that is not "different" from other clinical services. Advanced care needs and purchase of futile treatments lead to lost employment among families, increased family debt and high care costs, which are rarely disclosed due to their unwillingness to discuss their needs.

Conclusion

Our novel theoretical model is an essential first step to ensure complex interventions are plausible, with mechanisms of action that address the needs of relevant stakeholders. A family-centred approach with an oncology workforce skilled in communication and an

enabled patient population could increase access to palliative care, and improved outcomes may be attainable.

Article Summary

Key words: India, cancer, stigma, palliative care

What is already known?

- The WHO's Universal Health Coverage (UHC) goals specify that palliative care should be available for the 683,000 annual cancer deaths in India.

- A systematic review found few interventions and patchy delivery of care models in India, and a majority preference among advanced cancer patients for full information.

What are the new findings?

- Our novel exploratory model found that families conceal information from patients, and require professionals to collude in this.

- This stigmatising behaviour leads to unrealistic expectations, pursuit of futile and expensive treatment, compounded poverty, and a reduction of palliative care services to pain management.

What do the new findings imply?

- Interventions to improve communication and disclosure must focus on the family as communication gatekeepers.

- The success of activities to enhance policy and opioid availability are contingent in enhanced oncology-family-patient interactions if the UHC goals are to be achieved.

Strengths and limitations

- This is the first study to identify drivers for poor end-of-life care access from the perspective of patients, families and professionals in India

- The inclusion of all stakeholders optimise the potential for strategies to improve care for people with advanced disease

- The data are collected from one city in India and so the study may need replication in other parts of this diverse country

- We did not directly observe clinical encounters and so cannot verify information giving behaviours by clinicians

BACKGROUND

Low and middle income countries (LMIC) are predicted to bear 70% of global cancer cases by 2030 [1]. As LMIC industrialise, cancer incidence is predicted to rise five-fold [2]. Clinicians anticipate poorer cure rates compared to high income countries due to late presentation, lack of locally adapted protocols, and fewer resources [3]. Similarly, the provision of palliative care is woefully inadequate in LMIC, where the majority of palliative and end-of-life care is needed, due to later presentation, fewer curative options, ageing populations and rising cancer incidence [4].

Palliative care is a global human right [5], to be provided "throughout the illness course" within LMIC [6]. The World Health Assembly (WHA) resolution 67.19 calls for palliative care "integrated throughout the life course" [7]. The most recent iteration of the WHO Universal Health Coverage goals calls for the "full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and *palliative care*"[8].

There were an estimated 682,830 cancer deaths in India during 2012[9]. The WHO's Global Report categorises India as lacking integrated palliative care [10], with patchy activity [11]. Lack of prioritisation of palliative care at the Governmental level hampers adequate policy responses, resulting in restrictive regulation [12]. Opioid consumption in India for cancer pain relief is comparatively very low, with annual morphine equivalent milligrams per capita of 0.2377, compared to the global average of 58.11 [13]. A systematic review of the state of evidence for palliative care in India found very little evidence to inform appropriate models of care [14].

As in many other LMIC, Indian households affected by cancer report lower workforce participation, and higher rates of borrowing and asset sales, compounding their poverty [15]. Most out-of-pocket expenses are on futile investigations, treatment and expensive diagnostics [16]. While most Indian cancer patients prefer to know their diagnosis, around one quarter do not, and would prefer information to be communicated only to family members. Research is thus needed to identify the best ways to help guide physician-patient and

physician-family communication [17]. Understanding cultural beliefs that shape access and delivery of cancer palliative care in India is essential to formulating an appropriate response [18], but unfortunately, very little data currently exist to inform such a response. A qualitative study of oncologists in India suggests poor understanding among patients of the meaning of a cancer diagnosis, fear of contagion, and hopelessness in face of the diagnosis [19], with professionals sharing information with family members who then often make care decisions without involving the patient. It should be noted that these data were collected primarily in the context of communicating cancer diagnosis, not poor prognosis, and did not seek patient or family views.

The lack of awareness of prognosis and diagnosis among patients and poor coverage of palliative care in India is at odds with evidence that the vast majority (92%) of Indian cancer patients would wish to know the chance of a cure [20]. It is thus essential to understand the mechanisms that drive current communication practices and poor palliative care access. Among cancer populations in the USA, patient-doctor communication is negatively affected in patients with lung cancer due to stigma [21]. A small study of cancer survivors, oncologists and the general population cancer in India perceived both community and internalized stigma to be driven by their own and others' beliefs that cancer is the result of sins of the past life, with social rejection due to the lay belief that cancer is an infectious disease [22].

A plausible model is needed that draws upon the perspectives of advanced cancer patients, families and clinicians. This may explain the potential role of stigma in communication and identify potential responses to increase access to, and delivery of, appropriate and effective palliative care. The development of such a model will enable feasible acceptable and appropriate interventions to be developed and evaluated.

This exploratory study aimed to meet this need by developing a plausible evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

METHODS

Design

This cross-sectional, qualitative study used samples drawn from multiple populations, including advanced cancer patients, their family caregivers, and oncologists to inform a triangulated model across key stakeholder primary data.

Sample and setting

The current exploratory study was undertaken at a 1350 bed tertiary teaching and referral hospital in South India. Patients and their family members were referred to the study either by the nurse or the medical resident in the department of pain and palliative care. Patient eligibility criteria included being at least 18 years old, having a cancer diagnosis, being referred to the palliative care department, understanding and speaking either English or Kannada (the local language), and having an adult family member who was willing to be interviewed about their caregiving needs and experiences with palliative care. Family eligibility criteria included being at least 18 years old, caring for a patient who met the criteria above and consenting to data collection. In addition, they had to meet the following definition of informal caregiver, i.e. "unpaid, informal providers of one or more physical, social, practical and emotional tasks. In terms of their relationship to the patient, they may be a friend, partner, ex-partner, sibling, parent, child or other blood or non-blood relative" [23]. Oncologists interviewed were contacted directly by a faculty member in the department of pain and palliative medicine and had to have previously referred patients for palliative care. Our purposive sampling frame addressed the following characteristics: patient age, gender and primary malignancy, family caregiver relationship to patient, and clinical practice, with 10 per group (i.e. patient, family member, oncologist) to enable emergence of themes and integration of the stakeholder groups. The interviews were conducted over a twelve month period, starting in February 2017.

Procedures

The referring palliative medicine staff member introduced interested patients and family members to a study staff member, who explained the purpose of the study and obtained informed consent. The interviews were conducted in a private setting, separately for patients and family members, in the language of the participant's preference and typically took between 30-45 minutes. All procedures were approved by the Institutional Review Boards at St John's Medical College Hospital (ref: 222/2016), the University of California, San Francisco (ref: 174866), and Kings College London (ref: HR-16/17-3820).

Semi-structured interviews were conducted by trained study staff members, who had a Master's degree in psychology or social work. The interview guides were forward and back translated to ensure semantic equivalence [24] and addressed the patients' understanding of advanced disease, fears, social dimensions of disease (e.g. how cancer death may be socially stigmatized), their communication with family, friends and oncologists, their understanding, fears and acceptability of opioids, and concepts of incurable disease and palliation. The topic guide for family members addressed their understandings of advanced disease, fears, social dimensions of disease, communication with oncologists and information sharing/withholding from patients, their understanding of opioids and their fears and acceptability, and concepts of incurable disease and palliation. The interviews with oncologists addressed the role of stigma around death, dying, and opioid use in clinical management, disclosure, communication with patients and families, challenges to pain relief, and the perceived potential dangers and benefits of different treatment strategies. Patients and their family caregivers were interviewed separately to enable participants to express views as freely as possible.

Data management and analyses

All interviews were digitally recorded, transcribed and translated into English, if needed, prior to grounded theory analysis. This method was selected in line with our study aim of developing a novel explanatory evidence-based model of stigma and access to cancer palliative care for subsequent testing. Following reading and familiarisation with the

transcripts, an initial coding frame was developed with line-by-line coding (i.e. data reduction) by one researcher (RH) and the individual transcript coding and proposed frame were then reviewed by a second researcher (ME), and refined through consensus [25]. We then integrated the codes to develop the novel explanatory model (i.e. data complication). The coding frame, resultant model and interpretation were then discussed with the third researcher (SN), and agreed through consensus.

Public and patient involvement

Public and patients were not involved in the design or conduct of this research. This reflects the lack of patient advocacy currently in this field in India.

RESULTS

Sample description

Our planned sample size was met, with sample diversity achieved through the purposive sampling approach. Patient age ranged from 40-74, with a mix of male and female participants and primary malignancies (Table 1 below). The family caregivers were largely male, and were children and spouses of the patient. Oncologists spanned surgical, gynaecological, pulmonology, and radiation oncology with a range of 2-35 years of clinical practice.

Table 1 Sample characteristics

Patients & families			
Gender	Age	Primary malignancy	Family member: relationship to patient
Female	40	Ovary	Son
Female	65	Cervix	Son
Male	48	Cholangio carcinoma	Son
Female	48	Hepatocellular	Daughter
Male	74	Lung	Daughter
Male	49	Stomach	Son
Female	47	Cervix	Son
Female	60	Breast	Daughter
Female	42	Cervix	Husband
Female	64	Adenocarcinoma	Husband
Oncologists			
Designation	Years of qualified practice		Gender
Medical oncologist	15		Male
Radiation oncologist	30		Female
Radiation oncologist	6		Male
Surgical oncologist	2		Male
Gynaecology oncologist	35		Female
Surgical oncologist	5		Male
Surgical oncologist	2		Male
Gynaecology oncologist	10		Female
Pulmonologist	10		Female
Surgical oncologist	2		Male

Main findings

In Figure 1 we present the explanatory model generated from the data. In summary, the

model explains how the stigma associated with communicating a diagnosis of advanced

cancer is enacted by treating oncologists, family members and the community. This leads to

patient expectation of cure and uptake of futile treatment. Patients only present needs with

respect to pain and none within psychological, social or spiritual domains, likely due to the

lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and

families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack

of insight, palliative care clinicians view their services as underutilised, and patients perceive

palliative care simply as a pain management service that is not "different" from other clinical

services. The patient advanced care needs and purchase of futile treatments lead to lost

employment among family members, increased family debt and high care costs, which family members rarely disclosed to the treatment team due to their unwillingness to discuss their own needs.

INSERT FIGURE 1 HERE

Communication & understanding

- *Lack of disclosure: clinicians*

Although a range of behaviours were reported by clinicians in terms of disclosure of diagnosis and prognosis, the common approach was to withhold information from patients, or to actively give an inaccurate account, perpetuating the stigma of discussing death within medical and lay discourse.

> *"INTERVIEWER: Do you have patient asking you directly what is wrong with them and so how do you reply?*
>
> *ONCOLOGIST: "At time I will lie. 'I think you are improving or may take some more time', but I know that is not correct, but somehow, we have to balance." [Surgical oncologist]*

To never share accurate information was commonplace,

> *"Interviewer: Is it anytime or numbers of time that you have to actually initiate conversations with patient or their relatives about End of life care?*
>
> *Oncologist: Not actually………It's usually the patient family people ask like how the end is going to come, how patient is going to survive, how long he is going to survive then definitely we explain to them that how the end care will come………If the patients themselves are asking it is very, very rare, for ourselves to explain to them in such a case." [Radiation Oncologist].*

This reluctance to communicate honestly with patients was not restricted to earlier in the disease trajectory.

> *"INTERVIEWER: Do you actually have an end-of-life conversation?*
>
> *INTERVIEWEE: Not really. Initially, before the recurrence we do not talk.*
>
> *INTERVIEWER: No after the recurrence.*

INTERVIEWEE: No. After the recurrence, also at that point of time, we don't talk

about it." [Surgical oncologist].

- *Lack of disclosure: families*

The family is a major driver in non-disclosure to the patient of the stigmatising poor

prognosis. Even in cases where the clinician believed the patient should have full

information, the family may override this,

"We initially speak to the relatives first, and we do take their input as far as how much

to inform the patient first day. But very frankly, in our country, most of the relatives do

not want the diagnosis itself to be revealed to the patient, but we always make it a

point to mention that the patient has to know, has to understand what is the disease,

and what's happening, and the patient has to take the decision as far as therapy or

palliative care, whatever the thing, the patient has to be aware. But a very strong, this

thing, from the relatives not to tell the patient is put through us, most of the time, but

we do make it a point that this is something that the patient has to know, but I do

admit that we heed the relatives request not to reveal, or be more open to the

patient." [Gynaecological oncologist]

However, some oncologists believed that their patients could manage full disclosure;

"We underestimate the patient's capacity to observe the diagnosis and the treatment

and side effects etcetera including the prognosis. So, because as you said the

relatives first get to know the diagnosis and then get to know the treatment,

prognosis etcetera. There are a lot of uncertainties in the patient's mind as to the

diagnosis and the treatment and curability etcetera. So that has to be first addressed

so if we involve patient and take him into confidence and before we tell. This

happens even in educated patients also. The relatives might be less educated than

the patient, but they take the upper hand, they tell us that the patients cannot take

the shock of the diagnosis etcetera." [Medical Oncologist].

By acquiescing to the family direction not to disclose, many clinicians felt that this led to poorer care later towards the end of life,

"Yeah more than the patient there is some reluctant in part of the relatives. They

think if we discuss from that upfront before the time really has come for that they

think the end is very close. They think that the doctor has given up on the treatment

that treatment is not working so they have lot of apprehensions and negative feeling

associated with those discussions. So, many a time the treating physician is forced to

postpone all this really to the end of the terminally ill stage where the patient may not

be in a real position to take a decision or there are a lot of social thing that go with

the end of life which patient has to be given an opportunity to make decision while he

is in a real state of mind to make those decisions when he is not in real pain, when

he is not disoriented etcetera." [Medical Oncologist]*.*

Even if a clinician attempts to initiate direct communication with the patient, families may physically intervene,

"So many of times we know we face collusions that means our relatives are not

allowing us to say the diagnosis to the patient himself. In fact, they form a physical

barrier if you say right in front of us that, you know, showing us, different gestures

telling us not to tell the right one." [Radiation Oncologist].

Consistent with the oncologists' reports, family members described many instances when they chose to provide untruthful information to the patient regarding their illness, motivated by good intention that the patient may better "fight" the disease if they are unaware of prognosis

"First, we have to develop a feeling in them that we are here to support them. Then

we have to tell them that it is not a severe problem even though it is so, we have to

tell them that if this kind of treatment is taken it will improve her health, or, if there is a pain, then if she takes a tablet it will be under control. In this way, we fill in courage in them." [Daughter, hepatocellular cancer].

"I convinced him and got him discharged in the morning itself and got him here. The tests were done here and thought its ulcer and nothing related to cancer. Told him that it's just ulcer and not cancer and in endoscopy result, we got to know this is cancer." [Son, stomach cancer patient].

"We had told her this is starting stage but it was 4th stage. She felt bad when we told its starting stage also" [Son of cervical cancer patient].

- *Lack of disclosure: friends*

Patients and families described feeling stigmatised and socially ostracised from their community following the onset of illness,

Interviewer: "Your neighbours and the relatives who visit hospitals, have you faced any trouble from them?

Patient's son: There are changes, since one month their talking and talking behind our back has changed……..behaviour and all has changed. The way of talking will be different in front of them and in their back. It was different than before." [Son of cholangio carcinoma patient]

"Participant: That has become a big problem for us.

Interviewee: Will you tell more about it?

Participant: We have seen many such things. We have seen here also. Nothing has happened yet. After that only we came to hospital. In my village also no one speaks properly with us." [Husband of cervical cancer patient].

- *Choosing futile treatment & expecting cure*

Families and clinicians' behaviours regarding communication encouraged patients to pursue expensive and futile treatment. This exemplifies how the stigma of terminal illness can lead to adverse financial consequences for the family.

"Patient's daughter: About 3-4 months back, we had shown her once or twice, and again in 2013 took treatment in Hyderabad, again in Anantpur, Hindupur, Tumkur. Wherever people say treatment will be given, we have gone there and shown her…..We have visited about 10 hospitals. We have not got good results, no cure, even here. Nobody tells correctly about what has happened, what has to be done." [Son of cervical cancer patient].

"What may be our main issue in our present situation? We have to save our mother. That is our main issue. What are treatments available and where? Is it here in our country or is it available in other countries? Is there treatment for this may be it is in other country? We want to find it out and give it to her and we want to save her. That is our main concern now." [Daughter hepatocellular carcinoma cancer].

"What to expect, if there was reduction of pain, it would have been good. They won't tell anything. They told they will put chemotherapy injection. After we said okay for it, they told that we don't give guarantee for it. One injection is Rs 15000." [Son of stomach cancer patient].

"I am worried that this got this disease and how much ever we spend money on it, health is not improving. I am in this condition since 4-5 years and there is no improvement at all. I am not able to bear the pain". [Female 65 year old cervical cancer patient].

"By next year what I have thought is I have to get up and walk properly. I have to be like all others and walk like others and my disease should be cured. They have given me so much hopes that it will get better. I like to be like a normal person, by getting up and walk normally." [Female 48 hepatocellular cancer].

"I have to eat well if I have to do something related to my health. If I eat I will be fine. I know this 100%." [Female 64 adenocarcinoma patient].

Patient needs

Physical pain was the only concern described by patients and families, and was a major one for both groups. When psychological, social and spiritual needs were probed, none were described. The only social needs were the financial challenges described in relation to pursuing futile treatments (above).

However, the data do suggest that there may be psychological concerns that patients or families choose not to express to families or their clinical team,

"At present, what his feeling is he has to become better and he could be help us more or if he would have listened his wife's advice it would have been better. But anyway, he is not discussing anything openly." [Daughter of lung cancer patient].

This reluctance to share may result from the perceived necessity to focus on cure and active treatment,

"Interviewer: We are talking about your problem. Will you tell your problems to anyone?

Patient: No. I will not tell.

Interviewer: Why you won't tell?

Patient: Why to tell, what the use is by telling others. We only have to get it cured. We have to be quiet keeping this in our stomach, by believing god. If the ways I tell like how I am telling you, they also will spread this to other few by telling she has got big disease. They make the news big. If we eat food it will be inside your stomach, if you drink water it will be inside your stomach. Likewise why you want to tell this. You have to keep this in your stomach and be quiet." [Cervix cancer patient, 42].

Family needs

The only self-reported needs among family members were employment and financial ones. The desire to seek costly treatment was described by an oncologist,

"Basically all of them have financial problem if they have money then before this thing end of life I may ask 'do you want to take a second opinion'?" [Surgical oncologist]

Caregiving can also lead to unemployment,

"No problem as such. But the problem was of a job. When I came here to look after, I lost a job. When I came to look after my mother, my job was suspended. Other than this, no other problem. We don't want anything other than the disease getting cured. Now they are telling you need more money. We have got problem for money." [40 year old son of ovarian cancer patient]

As with patients, families chose not to share their distress with others, which suggests that expression of emotional concerns is highly stigmatised

"Interviewer: *Have you ever felt sharing this after seeing him suffer?*

Family member*: I don't like to tell to any relatives as we have to face our own difficulties"* [Son cervical cancer patient].

Family members described pain management for patients as improving wellbeing of family members,

"*If pain reduces its good for us. How soon it comes down, it's good for him as well as for us"* [Wife of adenocarcinoma patient].

Palliative care provision

- *Operates & understood as pain management*

Palliative care was commonly described by oncologists to patients and families as a pain management service

"*Without telling them that it is palliative care we refer to pain management. We say that, that is the pain doctor so you go there and sometimes there are symptoms which, you know, which we assumed about we tell them to go there, but we don't use the word palliative care at that time because they still have hope, they think that once you take palliative care all hope is lost."* [Gynaecological oncologist].

"*Interviewer: According to you what is palliative care?*

Patient: Palliative means pain remover.

Interviewer: Is the palliative care that you are taking is different from other cares?

Patient: No, it is not different." [Male 75 cancer lung]

This led to underutilisation of the available trained specialist palliative care team

"*The other problem is the availability of Palliative Care support. In fact, it has to start from the diagnosis itself, but then unfortunately most of us are underutilizing wherever Palliative Care specialists are available also. The services are*

underutilized only we are utilizing the services in terminally ill patients, End-of life-

care etcetera or only for pain management. So, it becomes equal to pain

management unfortunately, so that has to change.” [Medical Oncologist]

As a result of poor awareness of prognosis, the focus on pain, and the labelling of the

service as pain management, patients do not perceive palliative care as different to their

other care, although it successfully manages pain and optimises function

“This treatment is for the body pain so that she must not experience the body pain.

But this also is helping because pain is the main thing now. If medicines can be taken

at any condition then it is good. If there is pain she cannot do anything. Though she

cannot do her 100%, she can do her 60% work. She can eat, walk, so there is some

use.” [Daughter of patient with hepatocellular carcinoma].

This underuse is also evidence in the management to pain, with an example of emergency

room use instead of pre-emptive pain management planning

"*If I tell I have small pain, my brother, daughter or son-in-law will rush me to hospital”*
[Female 48 hepatocellular cancer]

Lastly, it was recognised that the responsibility for improving palliative care access lies with

the oncologists

“The mindset has to change from the consultant himself. Unfortunately, most of us

are not exposed to Palliative Care why we were doing our super speciality training

itself it starts from there and most of the hospitals including hospital like [hospital

name] don't have good Palliative Care team then we are not put there for training.

During training we have not posted there for long enough to really know the

difference that is made by the Palliative Care especially in the life of the patients and

the relatives especially terminally ill patients. So, it has to start from the specialists

themselves" [Medical Oncologist]

DISCUSSION

This is the first study to determine the role of stigma in advanced cancer in India, integrating

primary data from patients, family members and oncologists. Although there is a literature

identifying this as an area of importance and cultural specificity, this has lacked original data

or an explanatory model of the mechanisms incorporating all potential actors in stigmatising

processes, to inform which interventions might be theoretically plausible and acceptable.

This exploratory study has generated a novel model that identifies the role of stigma in

expressing needs in advanced cancer, communication and disclosure, and in accessing

palliative care. The multilevel model reveals the collusion between clinical teams and

families that leads to pursuit of expensive and futile treatment, poor insight on the part of

patients, and suboptimal use of the wide range of interventions available through palliative

care teams.

Stigma is enacted and perpetuated at all levels, including by clinicians who do not openly

communicate poor prognosis, family members who request this concealment, and by

services that are simply described as "pain management.". Interestingly, no evidence was

found of "opiophobia" among patient and families, only one of whom was aware of morphine.

The data highlight a dissonance between preference and practice, given that the vast

majority of Indian cancer patients prefer to know their diagnosis [17] and the chance of a cure

[20]. Interestingly, our data suggest that patients had problems other than pain, but were

unwilling to share these concerns. We have found previously among advanced cancer

patients in LMIC that poor patient insight regarding diagnosis and prognosis are associated with worse self-reported wellbeing [26], that communicating poor prognosis is a challenge for medical staff in LMIC [27], and that decision-making is likely to be made away from the patient [28].

The results of this study differ somewhat from our previous findings [29-34] on the prevalence and correlates of HIV-related stigma in this region. Stigma enacted by health care providers and family members were driven largely by blame and fear of infection, which led to endorsement of coercive policies, such as mandatory testing and prohibitions on marriage and child-bearing. It also led to unwillingness by both family members and health care staff to care for HIV-infected patients. While no such attitudes were reported in the current study, lack of communication was clearly an issue in the care of both patients diagnosed with HIV and with advanced cancer. Participants in both studies also reported frequent disease-related misconceptions and an unwillingness to discuss sensitive topics, such as a poor prognosis and, in both cases, family members appeared to feel shame over the diagnosis of their loved one. In both situations, this shame, together with misconceptions regarding the disease, fear and lack of communication likely drove stigma and led to sub-optimal treatment.

There are a number of limitations to this exploratory study. Firstly, we did not aim to collect data on the content of the clinical encounter and therefore it may be that oncologists share information but this is poorly understood. However, our data from oncologists and family members strongly contradict that possibility, as they describe requests to conceal information. Secondly, our data were only collected in one private, non-profit Indian medical college hospital and we strongly recommend the expansion of this model through primary data collection in other types of institutions and multiple parts of India. Third, there may have been both a sampling and participation bias in that those with insight but a poor reaction to the information may not have consented to participate.

Previous studies form Pacific Asia have found that, despite popular belief, people would prefer to be given full information regarding diagnosis and prognosis [35-38]. Lack of disclosure of prognosis and introduction to the goals of palliative care in this population may have an interesting outcome, in that patients are more willing to be referred to palliative care when it is described as "pain management". However, this must be very carefully balanced against the poor outcomes described- pursuit and payment of futile treatments, lack of disclosure of concerns, very low levels of insight, and clinician views of under-use of the range of care and support available through palliative care staff.

There is evidence from the field of HIV in India that stigma-reducing interventions are wanted, feasible and acceptable[39-41]. We have a number of recommendations from our findings that aim to improve access to palliative and end-of-life care for patients and families affected by advanced cancer in India. Firstly, in order for patients and families to claim their right to affordable palliative care under the Universal Health Coverage, oncologists and families must enact the right to information about diagnosis and prognosis. However, this has to be done in a feasible and acceptable way and not unduly add to distress. This requires an intervention that supports families to accept and share poor prognosis with the patient and community. Second, to enable this right to information, oncologists require interventions that can enable them to handle these difficult, ongoing conversations in a way that is acceptable to families. In the context of concealed prognosis and pursuit of futile treatment, information giving must be seen as a process and not a single event. Third, building on our first two recommendations, the intervention must focus on the central information gatekeeping role of the family, who are likely to make key decisions and to act as physical and emotional barriers to information sharing between the oncologist and patient. In high-income countries there is evidence to suggest that family meetings may enhance family-patient-team communication[42]. Fourth, our data suggests that patients conceal their concerns. Within the model this appears to be driven to the stigma surrounding diagnosis and poor prognosis that is enacted by collusion between clinicians and families, keeping the

patient's focus upon cure and recovery. Intervention must empower patients to share their concerns beyond physical pain, to the extent that they wish by reducing perceived or internalised stigma. This will require oncology and palliative care services to use terminology that identifies palliative care as being more than simply a physical pain service, and enabling families to hear patient distress. Fifth, interventions must be developed from an expanded theory of stigma in advanced cancer, refining our model from the exploratory data using data from a wider geographical sample of oncologists, patients and families in India.

Our novel theoretical model is an essential first step to ensure that any proposed complex intervention is plausible and has a proposed mechanism of action that addresses all relevant stakeholder populations. Taking a family-centred approach, with an oncology workforce skilled in communication and an enabled patient population may be feasible and acceptable. Through this, improved access to palliative care with improved outcomes may be attainable.

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CONTRIBUTOR STATEMENT

The study was conceived by ME SN and RH, SN was local PI and analysis was led by RH with ME and SN reviewing and agreeing the data coding frame. The interpretation of findings was jointly by RH, SN and ME, and all authors contributed to and approved the final manuscript. RH led the drafting of the manuscript with contribution and by all authors and final approval by all authors.

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DATA SHARING STATEMENT

The raw data (transcripts) are available from the corresponding author upon reasonable request by email.

COMPETING INTERESTS STATEMENT

The authors have no competing interests to declare.

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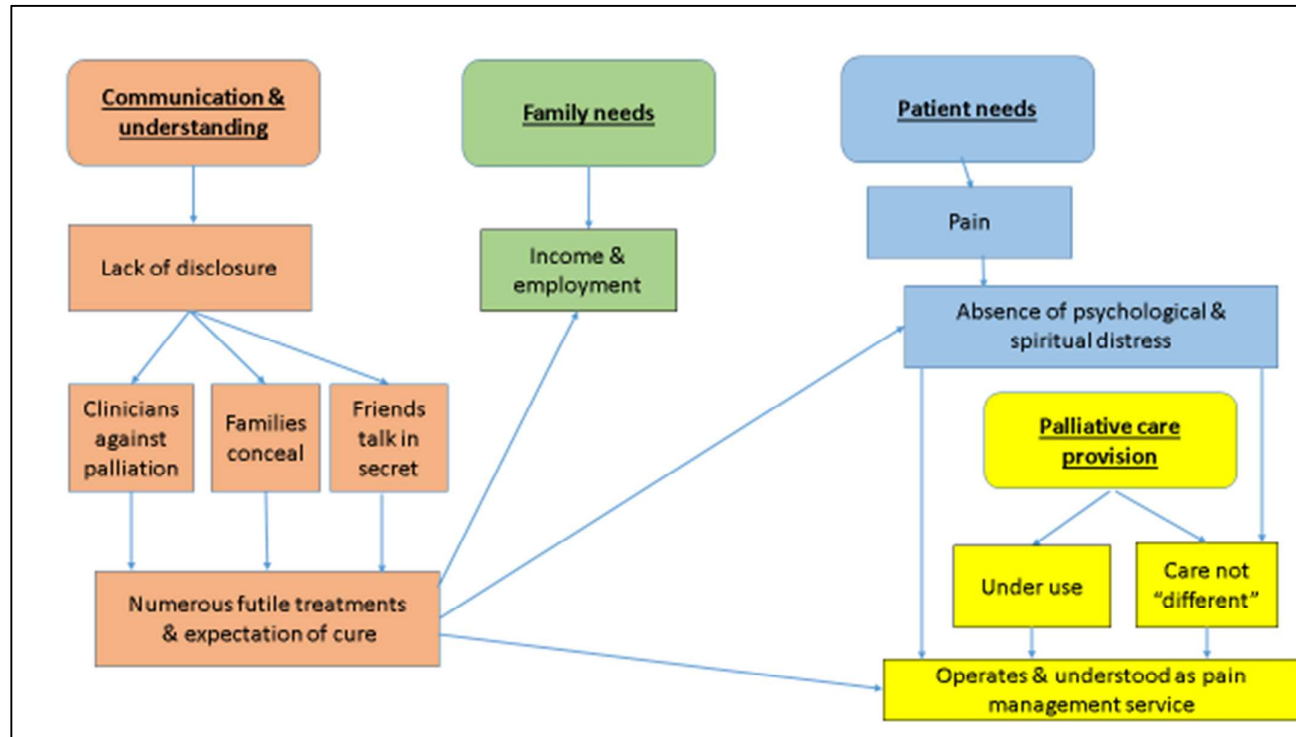
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5 **Figure 1 Explanatory model of the data**
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found PAGES 2 and 3
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported PAGES 4 and 5
Objectives	3	State specific objectives, including any prespecified hypotheses PAGE 5
Methods		
Study design	4	Present key elements of study design early in the paper PAGE 6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection PAGE 6 and 7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up NA
		Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls NA
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants PAGE 6-7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed NA
		Case-control study—For matched studies, give matching criteria and the number of controls per case NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable NA
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group NA
Bias	9	Describe any efforts to address potential sources of bias PAGE 7
Study size	10	Explain how the study size was arrived at PAGE 6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why NA
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding NA
		(*b*) Describe any methods used to examine subgroups and interactions NA
		(*c*) Explain how missing data were addressed NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed NA
		Case-control study—If applicable, explain how matching of cases and controls was addressed NA
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy NA
		(*e*) Describe any sensitivity analyses NA

Continued on next page

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed PAGES 8-9
		(b) Give reasons for non-participation at each stage NA
		(c) Consider use of a flow diagram NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders PAGES 8-9
		(b) Indicate number of participants with missing data for each variable of interest NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure NA
		Cross-sectional study—Report numbers of outcome events or summary measures NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included NA
		(*b*) Report category boundaries when continuous variables were categorized NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses PAGE 7-8

Discussion

Key results	18	Summarise key results with reference to study objectives PAGE 8-9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias PAGE 20
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence PAGE 19-22
Generalisability	21	Discuss the generalisability (external validity) of the study results PAGE 20

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based PAGE 23

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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A novel evidence-based multilevel model of stigma and barriers to cancer palliative care in India generated from qualitative in-depth interviews.

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A novel evidence-based multilevel model of stigma and barriers to cancer palliative

care in India generated from qualitative in-depth interviews

Richard Harding (corresponding author)

Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care

King's College London

Cicely Saunders Institute

Department of Palliative Care, Policy & Rehabilitation

Bessemer Road

London, UK

SE5 9PJ

Email: richard.harding@kcl.ac.uk

Tel: +44 (0) 207 848 5518

Shoba Nair

Department of Pain and Palliative Medicine

St John's Medical College Hospital

St John's National Academy of Health Sciences

Bengaluru, India

Maria L Ekstrand

Division of Prevention Science

Department of Medicine

University of California, San Francisco, USA

and

St John's Research Institute

St John's National Academy of Health Sciences

Bengaluru, India

Word count: 5487

Abstract

Introduction Palliative care coverage and opioid consumption in India are relatively low compared to global data. The literature suggests commonplace concealment and collusion in withholding information, but these hypotheses lack evidence.

Objectives This study aimed to develop an explanatory evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

Design This cross-sectional qualitative study sampled advanced cancer patients (n=10), their family caregivers (n=10), and oncologists (n=10). Grounded theory procedures were utilised to analyse transcripts, and a theoretical model generated.

Setting A tertiary teaching hospital in South India.

Results The model explains how stigma associated with communicating a diagnosis of advanced cancer is enacted by treating oncologists, family members and community. This leads to patient expectations of cure and futile treatment uptake. Patients only present needs with respect to pain and none within psychological, social or spiritual domains, likely due to the lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack of insight, palliative care clinicians view their services as underutilised, and patients perceive palliative care as a pain management service that is not "different" from other clinical services. Advanced care needs and purchase of futile treatments lead to lost employment among families, increased family debt and high care costs, which are rarely disclosed due to their unwillingness to discuss their needs.

Conclusion

Our novel theoretical model is an essential first step to ensure complex interventions are plausible, with mechanisms of action that address the needs of relevant stakeholders. A family-centred approach with an oncology workforce skilled in communication and an

enabled patient population could increase access to palliative care, and improved outcomes

may be attainable.

Strengths and limitations

- This is the first study to identify drivers for poor end-of-life care access from the

  perspective of patients, families and professionals in India

- The inclusion of all stakeholders optimise the potential for strategies to improve care

  for people with advanced disease

- The data are collected from one city in India and so the study may need replication in

  other parts of this diverse country

- We did not directly observe clinical encounters and so cannot verify information

  giving behaviours by clinicians

Key words: India, cancer, stigma, palliative care

BACKGROUND

Low and middle income countries (LMIC) are predicted to bear 70% of global cancer cases by 2030 [1]. As LMIC industrialise, cancer incidence is predicted to rise five-fold [2]. Clinicians anticipate poorer cure rates compared to high income countries due to late presentation, lack of locally adapted protocols, and fewer resources [3]. Similarly, the provision of palliative care is woefully inadequate in LMIC, where the majority of palliative and end-of-life care is needed, due to later presentation, fewer curative options, ageing populations and rising cancer incidence [4].

Palliative care is a global human right [5], to be provided "throughout the illness course" within LMIC [6]. The World Health Assembly (WHA) resolution 67.19 calls for palliative care "integrated throughout the life course" [7]. The most recent iteration of the WHO Universal Health Coverage goals calls for the "full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and *palliative care*"[8].

There were an estimated 815,100 cancer deaths in India during 2016[9]. The WHO's Global Report categorises India as lacking integrated palliative care [10], with patchy activity [11]. Lack of prioritisation of palliative care at the Governmental level hampers adequate policy responses, resulting in restrictive regulation [12]. Opioid consumption in India for cancer pain relief is comparatively very low, with annual morphine equivalent milligrams per capita of 0.2377, compared to the global average of 58.11 [13]. A systematic review of the state of evidence for palliative care in India found very little evidence to inform appropriate models of care [14].

As in many other LMIC, Indian households affected by cancer report lower workforce participation, and higher rates of borrowing and asset sales, compounding their poverty [15]. Most out-of-pocket expenses are on futile investigations, treatment and expensive diagnostics [16]. While most Indian cancer patients prefer to know their diagnosis, around one quarter do not, and would prefer information to be communicated only to family members. Research is thus needed to identify the best ways to help guide physician-patient and

physician-family communication [17]. Understanding cultural beliefs that shape access and delivery of cancer palliative care in India is essential to formulating an appropriate response [18], but unfortunately, very little data currently exist to inform such a response. A qualitative study of oncologists in India suggests poor understanding among patients of the meaning of a cancer diagnosis, fear of contagion, and hopelessness in face of the diagnosis [19], with professionals sharing information with family members who then often make care decisions without involving the patient. It should be noted that these data were collected primarily in the context of communicating cancer diagnosis, not poor prognosis, and did not seek patient or family views.

The lack of awareness of prognosis and diagnosis among patients and poor coverage of palliative care in India is at odds with evidence that the vast majority (92%) of Indian cancer patients would wish to know the chance of a cure [20]. It is thus essential to understand the mechanisms that drive current communication practices and poor palliative care access. Among cancer populations in the USA, patient-doctor communication is negatively affected in patients with lung cancer due to stigma [21]. A small study of cancer survivors, oncologists and the general population cancer in India perceived both community and internalized stigma to be driven by their own and others' beliefs that cancer is the result of sins of the past life, with social rejection due to the lay belief that cancer is an infectious disease [22].

An explanatory model is needed that draws upon the perspectives of advanced cancer patients, families and clinicians. This may explain the potential role of stigma in communication and identify potential responses to increase access to, and delivery of, appropriate and effective palliative care. The development of such a model will enable feasible acceptable and appropriate interventions to be developed and evaluated.

This exploratory study aimed to meet this need by developing an explanatory evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

METHODS

Design

This cross-sectional, qualitative study used samples drawn from multiple populations, including advanced cancer patients, their family caregivers, and oncologists to inform a triangulated model across key stakeholder primary data.

Sample and setting

The current exploratory study was undertaken at a 1350 bed tertiary teaching and referral hospital in South India. Patients and their family members were referred to the study either by the nurse or the medical resident in the department of pain and palliative care. Patient eligibility criteria included being at least 18 years old, having a cancer diagnosis, being referred to the palliative care department, understanding and speaking either English or Kannada (the local language), and having an adult family member who was willing to be interviewed about their caregiving needs and experiences with palliative care. Family eligibility criteria included being at least 18 years old, caring for a patient who met the criteria above and consenting to data collection. In addition, they had to meet the following definition of informal caregiver, i.e. "unpaid, informal providers of one or more physical, social, practical and emotional tasks. In terms of their relationship to the patient, they may be a friend, partner, ex-partner, sibling, parent, child or other blood or non-blood relative" [23]. Oncologists interviewed were contacted directly by a faculty member in the department of pain and palliative medicine and had to have previously referred patients for palliative care. Our purposive sampling frame addressed the following characteristics: patient age, gender and primary malignancy, family caregiver relationship to patient, and clinical practice, with 10 per group (i.e. patient, family member, oncologist) to enable emergence of themes and integration of the stakeholder groups. The interviews were conducted over a twelve month period, starting in February 2017.

Procedures

The referring palliative medicine staff member introduced interested patients and family members to a study staff member, who explained the purpose of the study and obtained informed consent. The interviews were conducted in a private setting, separately for patients and family members, in the language of the participant's preference and typically took between 30-45 minutes. All procedures were approved by the Institutional Review Boards at St John's Medical College Hospital (ref: 222/2016), the University of California, San Francisco (ref: 174866), and Kings College London (ref: HR-16/17-3820).

Semi-structured interviews were conducted by trained local Indian research staff members, who had a Master's degree in psychology or social work. Interviewers were independent of the referring clinic and had no prior interaction or relationship with participants. The interview guides were forward and back translated to ensure semantic equivalence [24] and addressed the patients' understanding of advanced disease, fears, social dimensions of disease (e.g. how cancer death may be socially stigmatized), their communication with family, friends and oncologists, their understanding, fears and acceptability of opioids, and concepts of incurable disease and palliation. The topic guide for family members addressed their understandings of advanced disease, fears, social dimensions of disease, communication with oncologists and information sharing/withholding from patients, their understanding of opioids and their fears and acceptability, and concepts of incurable disease and palliation. The interviews with oncologists addressed the role of stigma around death, dying, and opioid use in clinical management, disclosure, communication with patients and families, challenges to pain relief, and the perceived potential dangers and benefits of different treatment strategies. Patients and their family caregivers were interviewed separately to enable participants to express views as freely as possible.

Data management and analyses

All interviews were digitally recorded, transcribed verbatim in local language by bilingual research staff and translated into English at the Indian site, if needed, prior to grounded theory analysis. This method was selected in line with our study aim of developing a novel

explanatory evidence-based model of stigma and access to cancer palliative care for subsequent testing. Transcripts were then anononymised (e.g. potentially identifying information removed) emailed to the other research team members in the UK and USA. Following reading and familiarisation with the transcripts, an initial coding frame was developed with line-by-line coding (i.e. data reduction) of the entire dataset (i.e. patients, families and staff) by one researcher (RH) and the individual transcript coding and proposed frame were then reviewed by a second researcher (ME), and refined through consensus [25]. We then integrated the codes to develop the novel explanatory model (i.e. data complication). The coding frame, resultant model and interpretation were then discussed with the third researcher (SN), and agreed through consensus.

Public and patient involvement

Public and patients were not involved in the design or conduct of this research. This reflects the lack of patient advocacy currently in this field in India.

RESULTS

Sample description

Our planned sample size was met, with sample diversity achieved through the purposive sampling approach. Patient age ranged from 40-74, with a mix of male and female participants and primary malignancies (Table 1 below). The family caregivers were largely male, and were children and spouses of the patient. Oncologists spanned surgical, gynaecological, pulmonology, and radiation oncology with a range of 2-35 years of clinical practice.

Table 1 Sample characteristics

Patients & families			
Gender	Age	Primary malignancy	Family member: relationship to patient
Female	40	Ovary	Son
Female	65	Cervix	Son
Male	48	Cholangio carcinoma	Son
Female	48	Hepatocellular	Daughter
Male	74	Lung	Daughter
Male	49	Stomach	Son
Female	47	Cervix	Son
Female	60	Breast	Daughter
Female	42	Cervix	Husband
Female	64	Adenocarcinoma	Husband
Oncologists			
Designation	Years of qualified practice		Gender
Medical oncologist	15		Male
Radiation oncologist	30		Female
Radiation oncologist	6		Male
Surgical oncologist	2		Male
Gynaecology oncologist	35		Female
Surgical oncologist	5		Male
Surgical oncologist	2		Male
Gynaecology oncologist	10		Female
Pulmonologist	10		Female
Surgical oncologist	2		Male

Main findings

In Figure 1 we present the explanatory model generated from the data. In summary, the

model explains how the stigma associated with communicating a diagnosis of advanced

cancer is enacted by treating oncologists, family members and the community. This leads to

patient expectation of cure and uptake of futile treatment. Patients only present needs with

respect to pain and none within psychological, social or spiritual domains, likely due to the

lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and

families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack

of insight, palliative care clinicians view their services as underutilised, and patients perceive

palliative care simply as a pain management service that is not "different" from other clinical

services. The patient advanced care needs and purchase of futile treatments lead to lost

employment among family members, increased family debt and high care costs, which family members rarely disclosed to the treatment team due to their unwillingness to discuss their own needs.

INSERT FIGURE 1 HERE

Communication & understanding

- *Lack of disclosure: clinicians*

Although a range of behaviours were reported by clinicians in terms of disclosure of diagnosis and prognosis, the common approach was to withhold information from patients, or to actively give an inaccurate account, perpetuating the stigma of discussing death within medical and lay discourse.

> *"INTERVIEWER: Do you have patient asking you directly what is wrong with them*
>
> *and so how do you reply?*
>
> *ONCOLOGIST: "At time I will lie. 'I think you are improving or may take some more*
>
> *time', but I know that is not correct, but somehow, we have to balance." [Surgical*
>
> *oncologist]*

To never share accurate information was commonplace,

> *"Interviewer: Is it anytime or numbers of time that you have to actually initiate*
>
> *conversations with patient or their relatives about End of life care?*
>
> *Oncologist: Not actually………It's usually the patient family people ask like how the*
>
> *end is going to come, how patient is going to survive, how long he is going to survive*
>
> *then definitely we explain to them that how the end care will come………If the*
>
> *patients themselves are asking it is very, very rare, for ourselves to explain to them in*
>
> *such a case." [Radiation Oncologist].*

This reluctance to communicate honestly with patients was not restricted to earlier in the disease trajectory.

> *"INTERVIEWER: Do you actually have an end-of-life conversation?*
>
> *INTERVIEWEE: Not really. Initially, before the recurrence we do not talk.*
>
> *INTERVIEWER: No after the recurrence.*

INTERVIEWEE: No. After the recurrence, also at that point of time, we don't talk

about it." [Surgical oncologist].

- *Lack of disclosure: families*

The family is a major driver in non-disclosure to the patient of the stigmatising poor

prognosis. Even in cases where the clinician believed the patient should have full

information, the family may override this,

"We initially speak to the relatives first, and we do take their input as far as how much

to inform the patient first day. But very frankly, in our country, most of the relatives do

not want the diagnosis itself to be revealed to the patient, but we always make it a

point to mention that the patient has to know, has to understand what is the disease,

and what's happening, and the patient has to take the decision as far as therapy or

palliative care, whatever the thing, the patient has to be aware. But a very strong, this

thing, from the relatives not to tell the patient is put through us, most of the time, but

we do make it a point that this is something that the patient has to know, but I do

admit that we heed the relatives request not to reveal, or be more open to the

patient." [Gynaecological oncologist]

However, some oncologists believed that their patients could manage full disclosure;

"We underestimate the patient's capacity to observe the diagnosis and the treatment

and side effects etcetera including the prognosis. So, because as you said the

relatives first get to know the diagnosis and then get to know the treatment,

prognosis etcetera. There are a lot of uncertainties in the patient's mind as to the

diagnosis and the treatment and curability etcetera. So that has to be first addressed

so if we involve patient and take him into confidence and before we tell. This

happens even in educated patients also. The relatives might be less educated than

the patient, but they take the upper hand, they tell us that the patients cannot take

the shock of the diagnosis etcetera." [Medical Oncologist].

By acquiescing to the family direction not to disclose, many clinicians felt that this led to poorer care later towards the end of life,

"Yeah more than the patient there is some reluctant in part of the relatives. They

think if we discuss from that upfront before the time really has come for that they

think the end is very close. They think that the doctor has given up on the treatment

that treatment is not working so they have lot of apprehensions and negative feeling

associated with those discussions. So, many a time the treating physician is forced to

postpone all this really to the end of the terminally ill stage where the patient may not

be in a real position to take a decision or there are a lot of social thing that go with

the end of life which patient has to be given an opportunity to make decision while he

is in a real state of mind to make those decisions when he is not in real pain, when

he is not disoriented etcetera." [Medical Oncologist]*.*

Even if a clinician attempts to initiate direct communication with the patient, families may physically intervene,

"So many of times we know we face collusions that means our relatives are not

allowing us to say the diagnosis to the patient himself. In fact, they form a physical

barrier if you say right in front of us that, you know, showing us, different gestures

telling us not to tell the right one." [Radiation Oncologist].

Consistent with the oncologists' reports, family members described many instances when they chose to provide untruthful information to the patient regarding their illness, motivated by good intention that the patient may better "fight" the disease if they are unaware of prognosis

"First, we have to develop a feeling in them that we are here to support them. Then

we have to tell them that it is not a severe problem even though it is so, we have to

tell them that if this kind of treatment is taken it will improve her health, or, if there is a

pain, then if she takes a tablet it will be under control. In this way, we fill in courage in

them." [Daughter, hepatocellular cancer].

"I convinced him and got him discharged in the morning itself and got him here. The

tests were done here and thought its ulcer and nothing related to cancer. Told him

that it's just ulcer and not cancer and in endoscopy result, we got to know this is

cancer." [Son, stomach cancer patient].

"We had told her this is starting stage but it was 4th stage. She felt bad when we told

its starting stage also" [Son of cervical cancer patient]*.*

- *Lack of disclosure: friends*

Patients and families described feeling stigmatised and socially ostracised from their

community following the onset of illness,

Interviewer: "Your neighbours and the relatives who visit hospitals, have you faced

any trouble from them?

Patient's son: There are changes, since one month their talking and talking behind

our back has changed……..behaviour and all has changed. The way of talking will be

different in front of them and in their back. It was different than before." [Son of

cholangio carcinoma patient]

"Participant: That has become a big problem for us.

Interviewee: Will you tell more about it?

Participant: We have seen many such things. We have seen here also. Nothing has

happened yet. After that only we came to hospital. In my village also no one speaks

properly with us." [Husband of cervical cancer patient].

- *Choosing futile treatment & expecting cure*

Families and clinicians' behaviours regarding communication encouraged patients to pursue expensive and futile treatment. This exemplifies how the stigma of terminal illness can lead to adverse financial consequences for the family.

"Patient's daughter: About 3-4 months back, we had shown her once or twice, and again in 2013 took treatment in Hyderabad, again in Anantpur, Hindupur, Tumkur. Wherever people say treatment will be given, we have gone there and shown her…..We have visited about 10 hospitals. We have not got good results, no cure, even here. Nobody tells correctly about what has happened, what has to be done." [Son of cervical cancer patient].

"What may be our main issue in our present situation? We have to save our mother. That is our main issue. What are treatments available and where? Is it here in our country or is it available in other countries? Is there treatment for this may be it is in other country? We want to find it out and give it to her and we want to save her. That is our main concern now." [Daughter hepatocellular carcinoma cancer].

"What to expect, if there was reduction of pain, it would have been good. They won't tell anything. They told they will put chemotherapy injection. After we said okay for it, they told that we don't give guarantee for it. One injection is Rs 15000." [Son of stomach cancer patient].

"I am worried that this got this disease and how much ever we spend money on it, health is not improving. I am in this condition since 4-5 years and there is no improvement at all. I am not able to bear the pain". [Female 65 year old cervical cancer patient].

"By next year what I have thought is I have to get up and walk properly. I have to be like all others and walk like others and my disease should be cured. They have given me so much hopes that it will get better. I like to be like a normal person, by getting up and walk normally." [Female 48 hepatocellular cancer].

"I have to eat well if I have to do something related to my health. If I eat I will be fine. I know this 100%." [Female 64 adenocarcinoma patient].

Patient needs

Physical pain was the only concern described by patients and families, and was a major one for both groups. When psychological, social and spiritual needs were probed, none were described. The only social needs were the financial challenges described in relation to pursuing futile treatments (above).

However, the data do suggest that there may be psychological concerns that patients or families choose not to express to families or their clinical team,

"At present, what his feeling is he has to become better and he could be help us more or if he would have listened his wife's advice it would have been better. But anyway, he is not discussing anything openly." [Daughter of lung cancer patient].

This reluctance to share may result from the perceived necessity to focus on cure and active treatment,

"Interviewer: We are talking about your problem. Will you tell your problems to anyone?

Patient: No. I will not tell.

Interviewer: Why you won't tell?

Patient: Why to tell, what the use is by telling others. We only have to get it cured. We have to be quiet keeping this in our stomach, by believing god. If the ways I tell like how I am telling you, they also will spread this to other few by telling she has got big disease. They make the news big. If we eat food it will be inside your stomach, if you drink water it will be inside your stomach. Likewise why you want to tell this. You have to keep this in your stomach and be quiet." [Cervix cancer patient, 42].

Family needs

The only self-reported needs among family members were employment and financial ones. The desire to seek costly treatment was described by an oncologist,

"Basically all of them have financial problem if they have money then before this thing end of life I may ask 'do you want to take a second opinion'?" [Surgical oncologist]

Caregiving can also lead to unemployment,

"No problem as such. But the problem was of a job. When I came here to look after, I lost a job. When I came to look after my mother, my job was suspended. Other than this, no other problem. We don't want anything other than the disease getting cured. Now they are telling you need more money. We have got problem for money." [40 year old son of ovarian cancer patient]

As with patients, families chose not to share their distress with others, which suggests that expression of emotional concerns is highly stigmatised

"Interviewer: *Have you ever felt sharing this after seeing him suffer?*

Family member*: I don't like to tell to any relatives as we have to face our own*

difficulties" [Son cervical cancer patient].

Family members described pain management for patients as improving wellbeing of family

members,

"*If pain reduces its good for us. How soon it comes down, it's good for him as well as*

for us" [Wife of adenocarcinoma patient].

Palliative care provision

- *Operates & understood as pain management*

Palliative care was commonly described by oncologists to patients and families as a pain

management service

"Without telling them that it is palliative care we refer to pain management. We say

that, that is the pain doctor so you go there and sometimes there are symptoms

which, you know, which we assumed about we tell them to go there, but we don't use

the word palliative care at that time because they still have hope, they think that once

you take palliative care all hope is lost." [Gynaecological oncologist].

"Interviewer: According to you what is palliative care?

Patient: Palliative means pain remover.

Interviewer: Is the palliative care that you are taking is different from other cares?

Patient: No, it is not different." [Male 75 cancer lung]

This led to underutilisation of the available trained specialist palliative care team

"The other problem is the availability of Palliative Care support. In fact, it has to start

from the diagnosis itself, but then unfortunately most of us are underutilizing

wherever Palliative Care specialists are available also. The services are

underutilized only we are utilizing the services in terminally ill patients, End-of life-

care etcetera or only for pain management. So, it becomes equal to pain

management unfortunately, so that has to change." [Medical Oncologist]

As a result of poor awareness of prognosis, the focus on pain, and the labelling of the

service as pain management, patients do not perceive palliative care as different to their

other care, although it successfully manages pain and optimises function

"This treatment is for the body pain so that she must not experience the body pain.

But this also is helping because pain is the main thing now. If medicines can be taken

at any condition then it is good. If there is pain she cannot do anything. Though she

cannot do her 100%, she can do her 60% work. She can eat, walk, so there is some

use." [Daughter of patient with hepatocellular carcinoma].

This underuse is also evidence in the management to pain, with an example of emergency

room use instead of pre-emptive pain management planning

"*If I tell I have small pain, my brother, daughter or son-in-law will rush me to hospital*"

[Female 48 hepatocellular cancer]

Lastly, it was recognised that the responsibility for improving palliative care access lies with

the oncologists

"The mindset has to change from the consultant himself. Unfortunately, most of us

are not exposed to Palliative Care why we were doing our super speciality training

itself it starts from there and most of the hospitals including hospital like [hospital

name] don't have good Palliative Care team then we are not put there for training. During training we have not posted there for long enough to really know the difference that is made by the Palliative Care especially in the life of the patients and the relatives especially terminally ill patients. So, it has to start from the specialists themselves" [Medical Oncologist]

DISCUSSION

This is the first study to determine the role of stigma in advanced cancer in India, integrating primary data from patients, family members and oncologists. Although there is a literature identifying this as an area of importance and cultural specificity, this has lacked original data or an explanatory model of the mechanisms incorporating all potential actors in stigmatising processes, to inform which interventions might be theoretically plausible and acceptable.

This exploratory study has generated a novel model that identifies the role of stigma in expressing needs in advanced cancer, communication and disclosure, and in accessing palliative care. The multilevel model reveals the collusion between clinical teams and families that leads to pursuit of expensive and futile treatment, poor insight on the part of patients, and suboptimal use of the wide range of interventions available through palliative care teams.

Stigma is enacted and perpetuated at all levels, including by clinicians who do not openly communicate poor prognosis, family members who request this concealment, and by services that are simply described as "pain management.". Interestingly, no evidence was found of "opiophobia" among patient and families, only one of whom was aware of morphine.

The data highlight a dissonance between preference and practice, given that the vast majority of Indian cancer patients prefer to know their diagnosis [17] and the chance of a cure [20]. Interestingly, our data suggest that patients had problems other than pain, but were unwilling to share these concerns. We have found previously among advanced cancer

patients in LMIC that poor patient insight regarding diagnosis and prognosis are associated with worse self-reported wellbeing [26], that communicating poor prognosis is a challenge for medical staff in LMIC [27], and that decision-making is likely to be made away from the patient [28].

The results of this study differ somewhat from our previous findings [29-34] on the prevalence and correlates of HIV-related stigma in this region. Stigma enacted by health care providers and family members were driven largely by blame and fear of infection, which led to endorsement of coercive policies, such as mandatory testing and prohibitions on marriage and child-bearing. It also led to unwillingness by both family members and health care staff to care for HIV-infected patients. While no such attitudes were reported in the current study, lack of communication was clearly an issue in the care of both patients diagnosed with HIV and with advanced cancer. Participants in both studies also reported frequent disease-related misconceptions and an unwillingness to discuss sensitive topics, such as a poor prognosis and, in both cases, family members appeared to feel shame over the diagnosis of their loved one. In both situations, this shame, together with misconceptions regarding the disease, fear and lack of communication likely drove stigma and led to sub-optimal treatment.

There are a number of limitations to this exploratory study. Firstly, we did not aim to collect data on the content of the clinical encounter and therefore it may be that oncologists share information but this is poorly understood. However, our data from oncologists and family members strongly contradict that possibility, as they describe requests to conceal information. Secondly, our data were only collected in one private, non-profit Indian medical college hospital and we strongly recommend the expansion of this model through primary data collection in other types of institutions and multiple parts of India. Third, there may have been both a sampling and participation bias in that those with insight but a poor reaction to the information may not have consented to participate. We are not aware of any conflicts of interest in this study.

Previous studies form Pacific Asia have found that, despite popular belief, people would prefer to be given full information regarding diagnosis and prognosis [35-38]. Lack of disclosure of prognosis and introduction to the goals of palliative care in this population may have an interesting outcome, in that patients are more willing to be referred to palliative care when it is described as "pain management". However, this must be very carefully balanced against the poor outcomes described- pursuit and payment of futile treatments, lack of disclosure of concerns, very low levels of insight, and clinician views of under-use of the range of care and support available through palliative care staff.

There is evidence from the field of HIV in India that stigma-reducing interventions are wanted, feasible and acceptable [39-41]. We have a number of recommendations from our findings that aim to improve access to palliative and end-of-life care for patients and families affected by advanced cancer in India. Firstly, in order for patients and families to claim their right to affordable palliative care under the Universal Health Coverage, oncologists and families must enact the right to information about diagnosis and prognosis. However, this has to be done in a feasible and acceptable way and not unduly add to distress. This requires an intervention that supports families to accept and share poor prognosis with the patient and community. Second, to enable this right to information, oncologists require interventions that can enable them to handle these difficult, ongoing conversations in a way that is acceptable to families. In the context of concealed prognosis and pursuit of futile treatment, information giving must be seen as a process and not a single event. Third, building on our first two recommendations, the intervention must focus on the central information gatekeeping role of the family, who are likely to make key decisions and to act as physical and emotional barriers to information sharing between the oncologist and patient. In high-income countries there is evidence to suggest that family meetings may enhance family-patient-team communication [42]. Fourth, our data suggests that patients conceal their concerns. Within the model this appears to be driven to the stigma surrounding diagnosis

and poor prognosis that is enacted by collusion between clinicians and families, keeping the patient's focus upon cure and recovery. Intervention must empower patients to share their concerns beyond physical pain, to the extent that they wish by reducing perceived or internalised stigma. This will require oncology and palliative care services to use terminology that identifies palliative care as being more than simply a physical pain service, and enabling families to hear patient distress. Fifth, interventions must be developed from an expanded theory of stigma in advanced cancer, refining our model from the exploratory data using data from a wider geographical sample of oncologists, patients and families in India.

Our novel theoretical model is an essential first step to ensure that any proposed complex intervention is plausible and has a proposed mechanism of action that addresses all relevant stakeholder populations. Taking a family-centred approach, with an oncology workforce skilled in communication and an enabled patient population may be feasible and acceptable. Through this, improved access to palliative care with improved outcomes may be attainable.

CONTRIBUTOR STATEMENT

The study was conceived by ME SN and RH, SN was local PI and analysis was led by RH with ME and SN reviewing and agreeing the data coding frame. The interpretation of findings was jointly by RH, SN and ME, and all authors contributed to and approved the final

manuscript. RH led the drafting of the manuscript with contribution and by all authors and

final approval by all authors.

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DATA SHARING STATEMENT

The raw data (transcripts) are available from the corresponding author upon reasonable

request by email.

COMPETING INTERESTS STATEMENT

The authors have no competing interests to declare.

Figure 1 Explanatory model of the data

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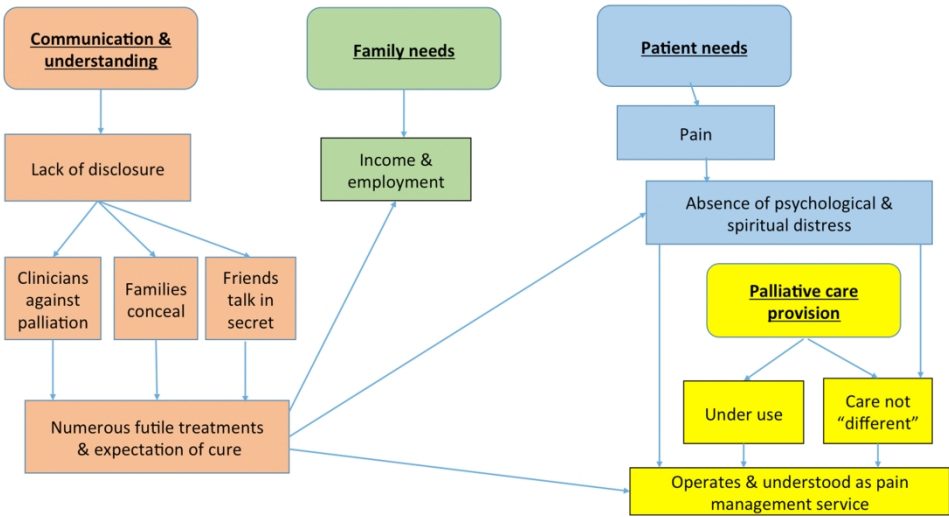
Figure 1 Explanatory model of the data

595x334mm (300 x 300 DPI)

SRQR Checklist HARDING

bmjopen-2018-024248 entitled "A novel evidence-based multilevel model of stigma and barriers to cancer palliative care in India generated from qualitative in-depth interviews."

SRQR number	Item	Met?
Title and abstract		
S1	Title Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	✓
S2	Abstract Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	✓
S3	Problem formulation Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	✓
S4	Purpose or research question Purpose of the study and specific objectives or questions	✓
Introduction		
S5	Qualitative approach and research paradigm Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale	✓
S6	Researcher characteristics and reflexivity Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	✓
S7	Context Setting/site and salient contextual factors; rationale.	✓
S8	Sampling strategy How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale	✓
S9	Ethical issues pertaining to human subjects Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	✓
S10	Data collection methods Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and	✓

	modification of procedures in response to evolving study findings; rationale	
S11	Data collection instruments and technologies Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	✓
S12	Units of study number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	✓
S13	Data processing Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/ deidentification of excerpts	✓
S14	Data analysis Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually	✓
S15	Techniques to enhance trustworthiness Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale.	✓
Results		
S16	Synthesis and interpretation Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	✓
S17	Links to empirical data Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	✓
Discussion		
S18	Integration with prior work, implications, transferability, and contribution(s) to the field. Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field.	✓
S19	Limitations Trustworthiness and limitations of findings	✓
S20	Conflicts of interest Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	✓
S21	Funding Sources of funding and other support; role of funders in data collection, interpretation, and reporting	✓

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A multilevel model of stigma and barriers to cancer palliative care in India generated from qualitative in-depth interviews.

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A multilevel model of stigma and barriers to cancer palliative care in India generated from qualitative in-depth interviews.

Richard Harding (corresponding author)

Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care

King's College London

Cicely Saunders Institute

Department of Palliative Care, Policy & Rehabilitation

Bessemer Road

London, UK

SE5 9PJ

Email: richard.harding@kcl.ac.uk

Tel: +44 (0) 207 848 5518

Shoba Nair

Department of Pain and Palliative Medicine

St John's Medical College Hospital

St John's National Academy of Health Sciences

Bengaluru, India

Maria L Ekstrand

Division of Prevention Science

Department of Medicine

University of California, San Francisco, USA

and

St John's Research Institute

St John's National Academy of Health Sciences

Bengaluru, India

Word count: 5487

Abstract

Introduction Palliative care coverage and opioid consumption in India are relatively low compared to global data. The literature suggests commonplace concealment and collusion in withholding information, but these hypotheses lack evidence.

Objectives This study aimed to develop an explanatory evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

Design This cross-sectional qualitative study sampled advanced cancer patients (n=10), their family caregivers (n=10), and oncologists (n=10). Grounded theory procedures were utilised to analyse transcripts, and a theoretical model generated.

Setting A tertiary teaching hospital in South India.

Results The model explains how stigma associated with communicating a diagnosis of advanced cancer is enacted by treating oncologists, family members and community. This leads to patient expectations of cure and futile treatment uptake. Patients only present needs with respect to pain and none within psychological, social or spiritual domains, likely due to the lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack of insight, palliative care clinicians view their services as underutilised, and patients perceive palliative care as a pain management service that is not "different" from other clinical services. Advanced care needs and purchase of futile treatments lead to lost employment among families, increased family debt and high care costs, which are rarely disclosed due to their unwillingness to discuss their needs.

Conclusion

Our novel theoretical model is an essential first step to ensure complex interventions are plausible, with mechanisms of action that address the needs of relevant stakeholders. A family-centred approach with an oncology workforce skilled in communication and an

enabled patient population could increase access to palliative care, and improved outcomes

may be attainable.

Strengths and limitations

- This is the first study to identify drivers for poor end-of-life care access from the

  perspective of patients, families and professionals in India

- The inclusion of all stakeholders optimise the potential for strategies to improve care

  for people with advanced disease

- The data are collected from one city in India and so the study may need replication in

  other parts of this diverse country

- We did not directly observe clinical encounters and so cannot verify information

  giving behaviours by clinicians

Key words: India, cancer, stigma, palliative care

BACKGROUND

Low and middle income countries (LMIC) are predicted to bear 70% of global cancer cases by 2030 [1]. As LMIC industrialise, cancer incidence is predicted to rise five-fold [2]. Clinicians anticipate poorer cure rates compared to high income countries due to late presentation, lack of locally adapted protocols, and fewer resources [3]. Similarly, the provision of palliative care is woefully inadequate in LMIC, where the majority of palliative and end-of-life care is needed, due to later presentation, fewer curative options, ageing populations and rising cancer incidence [4].

Palliative care is a global human right [5], to be provided "throughout the illness course" within LMIC [6]. The World Health Assembly (WHA) resolution 67.19 calls for palliative care "integrated throughout the life course" [7]. The most recent iteration of the WHO Universal Health Coverage goals calls for the "full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and *palliative care*"[8].

There were an estimated 815,100 cancer deaths in India during 2016[9]. The WHO's Global Report categorises India as lacking integrated palliative care [10], with patchy activity [11]. Lack of prioritisation of palliative care at the Governmental level hampers adequate policy responses, resulting in restrictive regulation [12]. Opioid consumption in India for cancer pain relief is comparatively very low, with annual morphine equivalent milligrams per capita of 0.2377, compared to the global average of 58.11 [13]. A systematic review of the state of evidence for palliative care in India found very little evidence to inform appropriate models of care [14].

As in many other LMIC, Indian households affected by cancer report lower workforce participation, and higher rates of borrowing and asset sales, compounding their poverty [15]. Most out-of-pocket expenses are on futile investigations, treatment and expensive diagnostics [16]. While most Indian cancer patients prefer to know their diagnosis, around one quarter do not, and would prefer information to be communicated only to family members. Research is thus needed to identify the best ways to help guide physician-patient and

physician-family communication [17]. Understanding cultural beliefs that shape access and delivery of cancer palliative care in India is essential to formulating an appropriate response [18], but unfortunately, very little data currently exist to inform such a response. A qualitative study of oncologists in India suggests poor understanding among patients of the meaning of a cancer diagnosis, fear of contagion, and hopelessness in face of the diagnosis [19], with professionals sharing information with family members who then often make care decisions without involving the patient. It should be noted that these data were collected primarily in the context of communicating cancer diagnosis, not poor prognosis, and did not seek patient or family views.

The lack of awareness of prognosis and diagnosis among patients and poor coverage of palliative care in India is at odds with evidence that the vast majority (92%) of Indian cancer patients would wish to know the chance of a cure [20]. It is thus essential to understand the mechanisms that drive current communication practices and poor palliative care access. Among cancer populations in the USA, patient-doctor communication is negatively affected in patients with lung cancer due to stigma [21]. A small study of cancer survivors, oncologists and the general population cancer in India perceived both community and internalized stigma to be driven by their own and others' beliefs that cancer is the result of sins of the past life, with social rejection due to the lay belief that cancer is an infectious disease [22].

An explanatory model is needed that draws upon the perspectives of advanced cancer patients, families and clinicians. This may explain the potential role of stigma in communication and identify potential responses to increase access to, and delivery of, appropriate and effective palliative care. The development of such a model will enable feasible acceptable and appropriate interventions to be developed and evaluated.

This exploratory study aimed to meet this need by developing an explanatory evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

METHODS

Design

This cross-sectional, qualitative study used samples drawn from multiple populations, including advanced cancer patients, their family caregivers, and oncologists to inform a triangulated model across key stakeholder primary data.

Sample and setting

The current exploratory study was undertaken at a 1350 bed tertiary teaching and referral hospital in South India. Patients and their family members were referred to the study either by the nurse or the medical resident in the department of pain and palliative care. Patient eligibility criteria included being at least 18 years old, having a cancer diagnosis, being referred to the palliative care department, understanding and speaking either English or Kannada (the local language), and having an adult family member who was willing to be interviewed about their caregiving needs and experiences with palliative care. Family eligibility criteria included being at least 18 years old, caring for a patient who met the criteria above and consenting to data collection. In addition, they had to meet the following definition of informal caregiver, i.e. "unpaid, informal providers of one or more physical, social, practical and emotional tasks. In terms of their relationship to the patient, they may be a friend, partner, ex-partner, sibling, parent, child or other blood or non-blood relative" [23]. Oncologists interviewed were contacted directly by a faculty member in the department of pain and palliative medicine and had to have previously referred patients for palliative care. Our purposive sampling frame addressed the following characteristics: patient age, gender and primary malignancy, family caregiver relationship to patient, and clinical practice, with 10 per group (i.e. patient, family member, oncologist) to enable emergence of themes and integration of the stakeholder groups. The interviews were conducted over a twelve month period, starting in February 2017.

Procedures

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The referring palliative medicine staff member introduced interested patients and family members to a study staff member, who explained the purpose of the study and obtained informed consent. The interviews were conducted in a private setting, separately for patients and family members, in the language of the participant's preference and typically took between 30-45 minutes. All procedures were approved by the Institutional Review Boards at St John's Medical College Hospital (ref: 222/2016), the University of California, San Francisco (ref: 174866), and Kings College London (ref: HR-16/17-3820).

Semi-structured interviews were conducted by trained local Indian research staff members, who had a Master's degree in psychology or social work. Interviewers were independent of the referring clinic and had no prior interaction or relationship with participants. The interview guides were forward and back translated to ensure semantic equivalence [24] and addressed the patients' understanding of advanced disease, fears, social dimensions of disease (e.g. how cancer death may be socially stigmatized), their communication with family, friends and oncologists, their understanding, fears and acceptability of opioids, and concepts of incurable disease and palliation. The topic guide for family members addressed their understandings of advanced disease, fears, social dimensions of disease, communication with oncologists and information sharing/withholding from patients, their understanding of opioids and their fears and acceptability, and concepts of incurable disease and palliation. The interviews with oncologists addressed the role of stigma around death, dying, and opioid use in clinical management, disclosure, communication with patients and families, challenges to pain relief, and the perceived potential dangers and benefits of different treatment strategies. Patients and their family caregivers were interviewed separately to enable participants to express views as freely as possible.

Data management and analyses

All interviews were digitally recorded, transcribed verbatim in local language by bilingual research staff and translated into English at the Indian site, if needed, prior to grounded theory analysis. This method was selected in line with our study aim of developing a novel

explanatory evidence-based model of stigma and access to cancer palliative care for

subsequent testing. Transcripts were then anononymised (e.g. potentially identifying

information removed) emailed to the other research team members in the UK and USA.

Following reading and familiarisation with the transcripts, an initial coding frame was

developed with line-by-line coding (i.e. data reduction) of the entire dataset (i.e. patients,

families and staff) by one researcher (RH) and the individual transcript coding and proposed

frame were then reviewed by a second researcher (ME), and refined through consensus [25].

We then integrated the codes to develop the novel explanatory model (i.e. data

complication). The coding frame, resultant model and interpretation were then discussed

with the third researcher (SN), and agreed through consensus.

Public and patient involvement

Public and patients were not involved in the design or conduct of this research. This reflects

the lack of patient advocacy currently in this field in India.

RESULTS

Sample description

Our planned sample size was met, with sample diversity achieved through the purposive

sampling approach. Patient age ranged from 40-74, with a majority of female patients

(n=7/10) (Table 1 below). The primary malignancy was cervix (n=3), ovary n=1,

hepatocellular n=1, adenocarcinoma n=1, breast n=1, stomach n=1, and cholangio

carcinoma n=1). The family caregivers were largely male, and were children and spouses of

the patient. Oncologists spanned surgical, gynaecological, pulmonology, and radiation

oncology with a range of 2-35 years of clinical practice.

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Table 1 Sample characteristics

Patients & families		
Gender	*Age*	*Family member: relationship to patient*
Female	40	Son
Female	65	Son
Male	48	Son
Female	48	Daughter
Male	74	Daughter
Male	49	Son
Female	47	Son
Female	60	Daughter
Female	42	Husband
Female	64	Husband
Oncologists		
Designation	*Years of qualified practice*	*Gender*
Medical oncologist	15	Male
Radiation oncologist	30	Female
Radiation oncologist	6	Male
Surgical oncologist	2	Male
Gynaecology oncologist	35	Female
Surgical oncologist	5	Male
Surgical oncologist	2	Male
Gynaecology oncologist	10	Female
Pulmonologist	10	Female
Surgical oncologist	2	Male

Main findings

In Figure 1 we present the explanatory model generated from the data. In summary, the

model explains how the stigma associated with communicating a diagnosis of advanced

cancer is enacted by treating oncologists, family members and the community. This leads to

patient expectation of cure and uptake of futile treatment. Patients only present needs with

respect to pain and none within psychological, social or spiritual domains, likely due to the

lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and

families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack

of insight, palliative care clinicians view their services as underutilised, and patients perceive

palliative care simply as a pain management service that is not "different" from other clinical

services. The patient advanced care needs and purchase of futile treatments lead to lost

employment among family members, increased family debt and high care costs, which

family members rarely disclosed to the treatment team due to their unwillingness to discuss

their own needs.

INSERT FIGURE 1 HERE

Communication & understanding

- *Lack of disclosure: clinicians*

Although a range of behaviours were reported by clinicians in terms of disclosure of

diagnosis and prognosis, the common approach was to withhold information from patients,

or to actively give an inaccurate account, perpetuating the stigma of discussing death within

medical and lay discourse.

> *"INTERVIEWER: Do you have patient asking you directly what is wrong with them*
>
> *and so how do you reply?*
>
> *ONCOLOGIST: "At time I will lie. 'I think you are improving or may take some more*
>
> *time', but I know that is not correct, but somehow, we have to balance." [Surgical*
>
> *oncologist]*

To never share accurate information was commonplace,

> *"Interviewer: Is it anytime or numbers of time that you have to actually initiate*
>
> *conversations with patient or their relatives about End of life care?*
>
> *Oncologist: Not actually………It's usually the patient family people ask like how the*
>
> *end is going to come, how patient is going to survive, how long he is going to survive*
>
> *then definitely we explain to them that how the end care will come………If the*
>
> *patients themselves are asking it is very, very rare, for ourselves to explain to them in*
>
> *such a case." [Radiation Oncologist].*

This reluctance to communicate honestly with patients was not restricted to earlier in the

disease trajectory.

> *"INTERVIEWER: Do you actually have an end-of-life conversation?*
>
> *INTERVIEWEE: Not really. Initially, before the recurrence we do not talk.*
>
> *INTERVIEWER: No after the recurrence.*

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INTERVIEWEE: No. After the recurrence, also at that point of time, we don't talk about it." [Surgical oncologist].

- *Lack of disclosure: families*

The family is a major driver in non-disclosure to the patient of the stigmatising poor prognosis. Even in cases where the clinician believed the patient should have full information, the family may override this,

"We initially speak to the relatives first, and we do take their input as far as how much to inform the patient first day. But very frankly, in our country, most of the relatives do not want the diagnosis itself to be revealed to the patient, but we always make it a point to mention that the patient has to know, has to understand what is the disease, and what's happening, and the patient has to take the decision as far as therapy or palliative care, whatever the thing, the patient has to be aware. But a very strong, this thing, from the relatives not to tell the patient is put through us, most of the time, but we do make it a point that this is something that the patient has to know, but I do admit that we heed the relatives request not to reveal, or be more open to the patient." [Gynaecological oncologist]

However, some oncologists believed that their patients could manage full disclosure;

"We underestimate the patient's capacity to observe the diagnosis and the treatment and side effects etcetera including the prognosis. So, because as you said the relatives first get to know the diagnosis and then get to know the treatment, prognosis etcetera. There are a lot of uncertainties in the patient's mind as to the diagnosis and the treatment and curability etcetera. So that has to be first addressed so if we involve patient and take him into confidence and before we tell. This happens even in educated patients also. The relatives might be less educated than

the patient, but they take the upper hand, they tell us that the patients cannot take

the shock of the diagnosis etcetera." [Medical Oncologist].

By acquiescing to the family direction not to disclose, many clinicians felt that this led to poorer care later towards the end of life,

"Yeah more than the patient there is some reluctant in part of the relatives. They

think if we discuss from that upfront before the time really has come for that they

think the end is very close. They think that the doctor has given up on the treatment

that treatment is not working so they have lot of apprehensions and negative feeling

associated with those discussions. So, many a time the treating physician is forced to

postpone all this really to the end of the terminally ill stage where the patient may not

be in a real position to take a decision or there are a lot of social thing that go with

the end of life which patient has to be given an opportunity to make decision while he

is in a real state of mind to make those decisions when he is not in real pain, when

he is not disoriented etcetera." [Medical Oncologist].

Even if a clinician attempts to initiate direct communication with the patient, families may physically intervene,

"So many of times we know we face collusions that means our relatives are not

allowing us to say the diagnosis to the patient himself. In fact, they form a physical

barrier if you say right in front of us that, you know, showing us, different gestures

telling us not to tell the right one." [Radiation Oncologist].

Consistent with the oncologists' reports, family members described many instances when they chose to provide untruthful information to the patient regarding their illness, motivated by good intention that the patient may better "fight" the disease if they are unaware of prognosis

"First, we have to develop a feeling in them that we are here to support them. Then

we have to tell them that it is not a severe problem even though it is so, we have to

tell them that if this kind of treatment is taken it will improve her health, or, if there is a pain, then if she takes a tablet it will be under control. In this way, we fill in courage in them." [Daughter, hepatocellular cancer].

"I convinced him and got him discharged in the morning itself and got him here. The tests were done here and thought its ulcer and nothing related to cancer. Told him that it's just ulcer and not cancer and in endoscopy result, we got to know this is cancer." [Son, stomach cancer patient].

"We had told her this is starting stage but it was 4th stage. She felt bad when we told its starting stage also" [Son of cervical cancer patient].

- *Lack of disclosure: friends*

Patients and families described feeling stigmatised and socially ostracised from their community following the onset of illness,

Interviewer: "Your neighbours and the relatives who visit hospitals, have you faced any trouble from them?

Patient's son: There are changes, since one month their talking and talking behind our back has changed……..behaviour and all has changed. The way of talking will be different in front of them and in their back. It was different than before." [Son of cholangio carcinoma patient]

"Participant: That has become a big problem for us.

Interviewee: Will you tell more about it?

Participant: We have seen many such things. We have seen here also. Nothing has happened yet. After that only we came to hospital. In my village also no one speaks properly with us." [Husband of cervical cancer patient].

- *Choosing futile treatment & expecting cure*

Families and clinicians' behaviours regarding communication encouraged patients to pursue

expensive and futile treatment. This exemplifies how the stigma of terminal illness can lead

to adverse financial consequences for the family.

"Patient's daughter: About 3-4 months back, we had shown her once or twice, and

again in 2013 took treatment in Hyderabad, again in Anantpur, Hindupur, Tumkur.

Wherever people say treatment will be given, we have gone there and shown

her…..We have visited about 10 hospitals. We have not got good results, no cure,

even here. Nobody tells correctly about what has happened, what has to be done."

[Son of cervical cancer patient].

"What may be our main issue in our present situation? We have to save our mother.

That is our main issue. What are treatments available and where? Is it here in our

country or is it available in other countries? Is there treatment for this may be it is in

other country? We want to find it out and give it to her and we want to save her. That

is our main concern now." [Daughter hepatocellular carcinoma cancer].

"What to expect, if there was reduction of pain, it would have been good. They won't

tell anything. They told they will put chemotherapy injection. After we said okay for it,

they told that we don't give guarantee for it. One injection is Rs 15000." [Son of

stomach cancer patient].

"I am worried that this got this disease and how much ever we spend money on it,

health is not improving. I am in this condition since 4-5 years and there is no

improvement at all. I am not able to bear the pain". [Female 65 year old cervical

cancer patient].

"By next year what I have thought is I have to get up and walk properly. I have to be like all others and walk like others and my disease should be cured. They have given me so much hopes that it will get better. I like to be like a normal person, by getting up and walk normally." [Female 48 hepatocellular cancer].

"I have to eat well if I have to do something related to my health. If I eat I will be fine. I know this 100%." [Female 64 adenocarcinoma patient].

Patient needs

Physical pain was the only concern described by patients and families, and was a major one for both groups. When psychological, social and spiritual needs were probed, none were described. The only social needs were the financial challenges described in relation to pursuing futile treatments (above).

However, the data do suggest that there may be psychological concerns that patients or families choose not to express to families or their clinical team,

"At present, what his feeling is he has to become better and he could be help us more or if he would have listened his wife's advice it would have been better. But anyway, he is not discussing anything openly." [Daughter of lung cancer patient].

This reluctance to share may result from the perceived necessity to focus on cure and active treatment,

"Interviewer: We are talking about your problem. Will you tell your problems to anyone?

Patient: No. I will not tell.

Interviewer: Why you won't tell?

Patient: Why to tell, what the use is by telling others. We only have to get it cured. We have to be quiet keeping this in our stomach, by believing god. If the ways I tell like how I am telling you, they also will spread this to other few by telling she has got big disease. They make the news big. If we eat food it will be inside your stomach, if you drink water it will be inside your stomach. Likewise why you want to tell this. You have to keep this in your stomach and be quiet." [Cervix cancer patient, 42].

Family needs

The only self-reported needs among family members were employment and financial ones. The desire to seek costly treatment was described by an oncologist,

"Basically all of them have financial problem if they have money then before this thing end of life I may ask 'do you want to take a second opinion'?" [Surgical oncologist]

Caregiving can also lead to unemployment,

"No problem as such. But the problem was of a job. When I came here to look after, I lost a job. When I came to look after my mother, my job was suspended. Other than this, no other problem. We don't want anything other than the disease getting cured. Now they are telling you need more money. We have got problem for money." [40 year old son of ovarian cancer patient]

As with patients, families chose not to share their distress with others, which suggests that expression of emotional concerns is highly stigmatised

"Interviewer: *Have you ever felt sharing this after seeing him suffer?*

Family member*: I don't like to tell to any relatives as we have to face our own difficulties"* [Son cervical cancer patient].

Family members described pain management for patients as improving wellbeing of family members,

"*If pain reduces its good for us. How soon it comes down, it's good for him as well as for us"* [Wife of adenocarcinoma patient].

Palliative care provision
- *Operates & understood as pain management*

Palliative care was commonly described by oncologists to patients and families as a pain management service

"*Without telling them that it is palliative care we refer to pain management. We say that, that is the pain doctor so you go there and sometimes there are symptoms which, you know, which we assumed about we tell them to go there, but we don't use the word palliative care at that time because they still have hope, they think that once you take palliative care all hope is lost."* [Gynaecological oncologist].

"*Interviewer: According to you what is palliative care?*
Patient: Palliative means pain remover.
Interviewer: Is the palliative care that you are taking is different from other cares?
Patient: No, it is not different." [Male 75 cancer lung]

This led to underutilisation of the available trained specialist palliative care team

"*The other problem is the availability of Palliative Care support. In fact, it has to start from the diagnosis itself, but then unfortunately most of us are underutilizing wherever Palliative Care specialists are available also. The services are*

underutilized only we are utilizing the services in terminally ill patients, End-of life-care etcetera or only for pain management. So, it becomes equal to pain management unfortunately, so that has to change." [Medical Oncologist]

As a result of poor awareness of prognosis, the focus on pain, and the labelling of the service as pain management, patients do not perceive palliative care as different to their other care, although it successfully manages pain and optimises function

"This treatment is for the body pain so that she must not experience the body pain. But this also is helping because pain is the main thing now. If medicines can be taken at any condition then it is good. If there is pain she cannot do anything. Though she cannot do her 100%, she can do her 60% work. She can eat, walk, so there is some use." [Daughter of patient with hepatocellular carcinoma].

This underuse is also evidence in the management to pain, with an example of emergency room use instead of pre-emptive pain management planning

"If I tell I have small pain, my brother, daughter or son-in-law will rush me to hospital" [Female 48 hepatocellular cancer]

Lastly, it was recognised that the responsibility for improving palliative care access lies with the oncologists

"The mindset has to change from the consultant himself. Unfortunately, most of us are not exposed to Palliative Care why we were doing our super speciality training itself it starts from there and most of the hospitals including hospital like [hospital

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name] don't have good Palliative Care team then we are not put there for training.

During training we have not posted there for long enough to really know the

difference that is made by the Palliative Care especially in the life of the patients and

the relatives especially terminally ill patients. So, it has to start from the specialists

themselves" [Medical Oncologist]

DISCUSSION

This is the first study to determine the role of stigma in advanced cancer in India, integrating primary data from patients, family members and oncologists. Although there is a literature identifying this as an area of importance and cultural specificity, this has lacked original data or an explanatory model of the mechanisms incorporating all potential actors in stigmatising processes, to inform which interventions might be theoretically plausible and acceptable.

This exploratory study has generated a novel model that identifies the role of stigma in expressing needs in advanced cancer, communication and disclosure, and in accessing palliative care. The multilevel model reveals the collusion between clinical teams and families that leads to pursuit of expensive and futile treatment, poor insight on the part of patients, and suboptimal use of the wide range of interventions available through palliative care teams.

Stigma is enacted and perpetuated at all levels, including by clinicians who do not openly communicate poor prognosis, family members who request this concealment, and by services that are simply described as "pain management.". Interestingly, no evidence was found of "opiophobia" among patient and families, only one of whom was aware of morphine.

The data highlight a dissonance between preference and practice, given that the vast majority of Indian cancer patients prefer to know their diagnosis [17] and the chance of a cure [20]. Interestingly, our data suggest that patients had problems other than pain, but were unwilling to share these concerns. We have found previously among advanced cancer

patients in LMIC that poor patient insight regarding diagnosis and prognosis are associated with worse self-reported wellbeing [26], that communicating poor prognosis is a challenge for medical staff in LMIC [27], and that decision-making is likely to be made away from the patient [28].

The results of this study differ somewhat from our previous findings [29-34] on the prevalence and correlates of HIV-related stigma in this region. Stigma enacted by health care providers and family members were driven largely by blame and fear of infection, which led to endorsement of coercive policies, such as mandatory testing and prohibitions on marriage and child-bearing. It also led to unwillingness by both family members and health care staff to care for HIV-infected patients. While no such attitudes were reported in the current study, lack of communication was clearly an issue in the care of both patients diagnosed with HIV and with advanced cancer. Participants in both studies also reported frequent disease-related misconceptions and an unwillingness to discuss sensitive topics, such as a poor prognosis and, in both cases, family members appeared to feel shame over the diagnosis of their loved one. In both situations, this shame, together with misconceptions regarding the disease, fear and lack of communication likely drove stigma and led to sub-optimal treatment.

There are a number of limitations to this exploratory study. Firstly, we did not aim to collect data on the content of the clinical encounter and therefore it may be that oncologists share information but this is poorly understood. However, our data from oncologists and family members strongly contradict that possibility, as they describe requests to conceal information. Secondly, our data were only collected in one private, non-profit Indian medical college hospital and we strongly recommend the expansion of this model through primary data collection in other types of institutions and multiple parts of India. Third, there may have been both a sampling and participation bias in that those with insight but a poor reaction to the information may not have consented to participate. We are not aware of any conflicts of interest in this study.

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Previous studies form Pacific Asia have found that, despite popular belief, people would prefer to be given full information regarding diagnosis and prognosis [35-38]. Lack of disclosure of prognosis and introduction to the goals of palliative care in this population may have an interesting outcome, in that patients are more willing to be referred to palliative care when it is described as "pain management". However, this must be very carefully balanced against the poor outcomes described- pursuit and payment of futile treatments, lack of disclosure of concerns, very low levels of insight, and clinician views of under-use of the range of care and support available through palliative care staff.

There is evidence from the field of HIV in India that stigma-reducing interventions are wanted, feasible and acceptable[39-41] .We have a number of recommendations from our findings that aim to improve access to palliative and end-of-life care for patients and families affected by advanced cancer in India. Firstly, in order for patients and families to claim their right to affordable palliative care under the Universal Health Coverage, oncologists and families must enact the right to information about diagnosis and prognosis. However, this has to be done in a feasible and acceptable way and not unduly add to distress. This requires an intervention that supports families to accept and share poor prognosis with the patient and community. Second, to enable this right to information, oncologists require interventions that can enable them to handle these difficult, ongoing conversations in a way that is acceptable to families. In the context of concealed prognosis and pursuit of futile treatment, information giving must be seen as a process and not a single event. Third, building on our first two recommendations, the intervention must focus on the central information gatekeeping role of the family, who are likely to make key decisions and to act as physical and emotional barriers to information sharing between the oncologist and patient. In high-income countries there is evidence to suggest that family meetings may enhance family-patient-team communication[42]. Fourth, our data suggests that patients conceal their concerns. Within the model this appears to be driven to the stigma surrounding diagnosis

and poor prognosis that is enacted by collusion between clinicians and families, keeping the patient's focus upon cure and recovery. Intervention must empower patients to share their concerns beyond physical pain, to the extent that they wish by reducing perceived or internalised stigma. This will require oncology and palliative care services to use terminology that identifies palliative care as being more than simply a physical pain service, and enabling families to hear patient distress. Fifth, interventions must be developed from an expanded theory of stigma in advanced cancer, refining our model from the exploratory data using data from a wider geographical sample of oncologists, patients and families in India.

Our novel theoretical model is an essential first step to ensure that any proposed complex intervention is plausible and has a proposed mechanism of action that addresses all relevant stakeholder populations. Taking a family-centred approach, with an oncology workforce skilled in communication and an enabled patient population may be feasible and acceptable. Through this, improved access to palliative care with improved outcomes may be attainable.

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CONTRIBUTOR STATEMENT

The study was conceived by ME SN and RH, SN was local PI and analysis was led by RH with ME and SN reviewing and agreeing the data coding frame. The interpretation of findings was jointly by RH, SN and ME, and all authors contributed to and approved the final

manuscript. RH led the drafting of the manuscript with contribution and by all authors and

final approval by all authors.

DATA SHARING STATEMENT

The raw data (transcripts) are available from the corresponding author upon reasonable

request by email.

COMPETING INTERESTS STATEMENT

The authors have no competing interests to declare.

Figure 1 Explanatory model of the data

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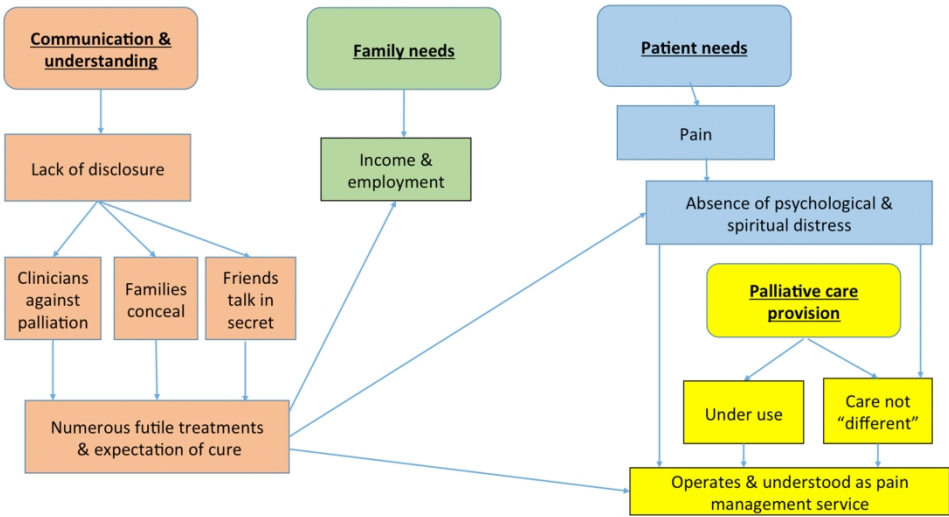
Figure 1 Explanatory model of the data

595x334mm (300 x 300 DPI)

SRQR Checklist HARDING

bmjopen-2018-024248 entitled "A novel evidence-based multilevel model of stigma and barriers to cancer palliative care in India generated from qualitative in-depth interviews."

SRQR number	Item	Met?
Title and abstract		
S1	Title Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	✓
S2	Abstract Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	✓
S3	Problem formulation Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	✓
S4	Purpose or research question Purpose of the study and specific objectives or questions	✓
Introduction		
S5	Qualitative approach and research paradigm Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale	✓
S6	Researcher characteristics and reflexivity Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	✓
S7	Context Setting/site and salient contextual factors; rationale.	✓
S8	Sampling strategy How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale	✓
S9	Ethical issues pertaining to human subjects Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	✓
S10	Data collection methods Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and	✓

	modification of procedures in response to evolving study findings; rationale	
S11	Data collection instruments and technologies Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	✓
S12	Units of study number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	✓
S13	Data processing Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/ deidentification of excerpts	✓
S14	Data analysis Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually	✓
S15	Techniques to enhance trustworthiness Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale.	✓
Results		
S16	Synthesis and interpretation Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	✓
S17	Links to empirical data Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	✓
Discussion		
S18	Integration with prior work, implications, transferability, and contribution(s) to the field. Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field.	✓
S19	Limitations Trustworthiness and limitations of findings	✓
S20	Conflicts of interest Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	✓
S21	Funding Sources of funding and other support; role of funders in data collection, interpretation, and reporting	✓

BMJ Open

A multilevel model of stigma and barriers to cancer palliative care in India: a qualitative study.

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A multilevel model of stigma and barriers to cancer palliative care in India: a qualitative study

Richard Harding (corresponding author)

Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care

King's College London

Cicely Saunders Institute

Department of Palliative Care, Policy & Rehabilitation

Bessemer Road

London, UK

SE5 9PJ

Email: richard.harding@kcl.ac.uk

Tel: +44 (0) 207 848 5518

Shoba Nair

Department of Pain and Palliative Medicine

St John's Medical College Hospital

St John's National Academy of Health Sciences

Bengaluru, India

Maria L Ekstrand

Division of Prevention Science

Department of Medicine

University of California, San Francisco, USA

and

St John's Research Institute

St John's National Academy of Health Sciences

Bengaluru, India

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Abstract

Introduction Palliative care coverage and opioid consumption in India are relatively low compared to global data. The literature suggests commonplace concealment and collusion in withholding information, but these hypotheses lack evidence.

Objectives This study aimed to develop an explanatory evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

Design This cross-sectional qualitative study sampled advanced cancer patients (n=10), their family caregivers (n=10), and oncologists (n=10). Grounded theory procedures were utilised to analyse transcripts, and a theoretical model generated.

Setting A tertiary teaching hospital in South India.

Results The model explains how stigma associated with communicating a diagnosis of advanced cancer is enacted by treating oncologists, family members and community. This leads to patient expectations of cure and futile treatment uptake. Patients only present needs with respect to pain and none within psychological, social or spiritual domains, likely due to the lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack of insight, palliative care clinicians view their services as underutilised, and patients perceive palliative care as a pain management service that is not "different" from other clinical services. Advanced care needs and purchase of futile treatments lead to lost employment among families, increased family debt and high care costs, which are rarely disclosed due to their unwillingness to discuss their needs.

Conclusion

Our novel theoretical model is an essential first step to ensure complex interventions are plausible, with mechanisms of action that address the needs of relevant stakeholders. A family-centred approach with an oncology workforce skilled in communication and an

enabled patient population could increase access to palliative care, and improved outcomes

may be attainable.

Strengths and limitations

- This is the first study to identify drivers for poor end-of-life care access from the

  perspective of patients, families and professionals in India

- The inclusion of all stakeholders optimise the potential for strategies to improve care

  for people with advanced disease

- The data are collected from one city in India and so the study may need replication in

  other parts of this diverse country

- We did not directly observe clinical encounters and so cannot verify information

  giving behaviours by clinicians

Key words: India, cancer, stigma, palliative care

BACKGROUND

Low and middle income countries (LMIC) are predicted to bear 70% of global cancer cases by 2030 [1]. As LMIC industrialise, cancer incidence is predicted to rise five-fold [2]. Clinicians anticipate poorer cure rates compared to high income countries due to late presentation, lack of locally adapted protocols, and fewer resources [3]. Similarly, the provision of palliative care is woefully inadequate in LMIC, where the majority of palliative and end-of-life care is needed, due to later presentation, fewer curative options, ageing populations and rising cancer incidence [4].

Palliative care is a global human right [5], to be provided "throughout the illness course" within LMIC [6]. The World Health Assembly (WHA) resolution 67.19 calls for palliative care "integrated throughout the life course" [7]. The most recent iteration of the WHO Universal Health Coverage goals calls for the "full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and *palliative care*" [8].

There were an estimated 815,100 cancer deaths in India during 2016 [9]. The WHO's Global Report categorises India as lacking integrated palliative care [10], with patchy activity [11]. Lack of prioritisation of palliative care at the Governmental level hampers adequate policy responses, resulting in restrictive regulation [12]. Opioid consumption in India for cancer pain relief is comparatively very low, with annual morphine equivalent milligrams per capita of 0.2377, compared to the global average of 58.11 [13]. A systematic review of the state of evidence for palliative care in India found very little evidence to inform appropriate models of care [14].

As in many other LMIC, Indian households affected by cancer report lower workforce participation, and higher rates of borrowing and asset sales, compounding their poverty [15]. Most out-of-pocket expenses are on futile investigations, treatment and expensive diagnostics [16]. While most Indian cancer patients prefer to know their diagnosis, around one quarter do not, and would prefer information to be communicated only to family members. Research is thus needed to identify the best ways to help guide physician-patient and

physician-family communication [17]. Understanding cultural beliefs that shape access and delivery of cancer palliative care in India is essential to formulating an appropriate response [18], but unfortunately, very little data currently exist to inform such a response. A qualitative study of oncologists in India suggests poor understanding among patients of the meaning of a cancer diagnosis, fear of contagion, and hopelessness in face of the diagnosis [19], with professionals sharing information with family members who then often make care decisions without involving the patient. It should be noted that these data were collected primarily in the context of communicating cancer diagnosis, not poor prognosis, and did not seek patient or family views.

The lack of awareness of prognosis and diagnosis among patients and poor coverage of palliative care in India is at odds with evidence that the vast majority (92%) of Indian cancer patients would wish to know the chance of a cure [20]. It is thus essential to understand the mechanisms that drive current communication practices and poor palliative care access. Among cancer populations in the USA, patient-doctor communication is negatively affected in patients with lung cancer due to stigma [21]. A small study of cancer survivors, oncologists and the general population cancer in India perceived both community and internalized stigma to be driven by their own and others' beliefs that cancer is the result of sins of the past life, with social rejection due to the lay belief that cancer is an infectious disease [22].

An explanatory model is needed that draws upon the perspectives of advanced cancer patients, families and clinicians. This may explain the potential role of stigma in communication and identify potential responses to increase access to, and delivery of, appropriate and effective palliative care. The development of such a model will enable feasible acceptable and appropriate interventions to be developed and evaluated.

This exploratory study aimed to meet this need by developing an explanatory evidence-based model of stigma, communication and access to cancer palliative care in India that can be used to develop, test and implement future interventions.

METHODS

Design

This cross-sectional, qualitative study used samples drawn from multiple populations, including advanced cancer patients, their family caregivers, and oncologists to inform a triangulated model across key stakeholder primary data.

Sample and setting

The current exploratory study was undertaken at a 1350 bed tertiary teaching and referral hospital in South India. Patients and their family members were referred to the study either by the nurse or the medical resident in the department of pain and palliative care. Patient eligibility criteria included being at least 18 years old, having a cancer diagnosis, being referred to the palliative care department, understanding and speaking either English or Kannada (the local language), and having an adult family member who was willing to be interviewed about their caregiving needs and experiences with palliative care. Family eligibility criteria included being at least 18 years old, caring for a patient who met the criteria above and consenting to data collection. In addition, they had to meet the following definition of informal caregiver, i.e. "unpaid, informal providers of one or more physical, social, practical and emotional tasks. In terms of their relationship to the patient, they may be a friend, partner, ex-partner, sibling, parent, child or other blood or non-blood relative" [23]. Oncologists interviewed were contacted directly by a faculty member in the department of pain and palliative medicine and had to have previously referred patients for palliative care. Our purposive sampling frame addressed the following characteristics: patient age, gender and primary malignancy, family caregiver relationship to patient, and clinical practice, with 10 per group (i.e. patient, family member, oncologist) to enable emergence of themes and integration of the stakeholder groups. The interviews were conducted over a twelve month period, starting in February 2017.

Procedures

The referring palliative medicine staff member introduced interested patients and family

members to a study staff member, who explained the purpose of the study and obtained

informed consent. The interviews were conducted in a private setting, separately for patients

and family members, in the language of the participant's preference and typically took

between 30-45 minutes. All procedures were approved by the Institutional Review Boards at

St John's Medical College Hospital (ref: 222/2016), the University of California, San

Francisco (ref: 174866), and Kings College London (ref: HR-16/17-3820).

Semi-structured interviews were conducted by trained local Indian research staff members,

who had a Master's degree in psychology or social work. Interviewers were independent of

the referring clinic and had no prior interaction or relationship with participants. The interview

guides were forward and back translated to ensure semantic equivalence [24] and addressed

the patients' understanding of advanced disease, fears, social dimensions of disease (e.g.

how cancer death may be socially stigmatized), their communication with family, friends and

oncologists, their understanding, fears and acceptability of opioids, and concepts of

incurable disease and palliation. The topic guide for family members addressed their

understandings of advanced disease, fears, social dimensions of disease, communication

with oncologists and information sharing/withholding from patients, their understanding of

opioids and their fears and acceptability, and concepts of incurable disease and palliation.

The interviews with oncologists addressed the role of stigma around death, dying, and opioid

use in clinical management, disclosure, communication with patients and families,

challenges to pain relief, and the perceived potential dangers and benefits of different

treatment strategies. Patients and their family caregivers were interviewed separately to

enable participants to express views as freely as possible.

Data management and analyses

All interviews were digitally recorded, transcribed verbatim in local language by bilingual

research staff and translated into English at the Indian site, if needed, prior to grounded

theory analysis. This method was selected in line with our study aim of developing a novel

explanatory evidence-based model of stigma and access to cancer palliative care for

subsequent testing. Transcripts were then anononymised (e.g. potentially identifying

information removed) emailed to the other research team members in the UK and USA.

Following reading and familiarisation with the transcripts, an initial coding frame was

developed with line-by-line coding (i.e. data reduction) of the entire dataset (i.e. patients,

families and staff) by one researcher (RH) and the individual transcript coding and proposed

frame were then reviewed by a second researcher (ME), and refined through consensus [25].

We then integrated the codes to develop the novel explanatory model (i.e. data

complication). The coding frame, resultant model and interpretation were then discussed

with the third researcher (SN), and agreed through consensus.

Public and patient involvement

Public and patients were not involved in the design or conduct of this research. This reflects

the lack of patient advocacy currently in this field in India.

RESULTS

Sample description

Our planned sample size was met, with sample diversity achieved through the purposive

sampling approach. Patient age ranged from 40-74, with a majority of female patients

(n=7/10) (Table 1 below). The primary malignancy was cervix (n=3), ovary n=1,

hepatocellular n=1, adenocarcinoma n=1, breast n=1, stomach n=1, and cholangio

carcinoma n=1). The family caregivers were largely male, and were children and spouses of

the patient. Oncologists spanned surgical, gynaecological, pulmonology, and radiation

oncology with a range of 2-35 years of clinical practice.

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Table 1 Sample characteristics

Patients & families		
Patient gender	*Patient age*	*Family member: relationship to patient*
Female	36-40	Son
Female	61-65	Son
Male	46-50	Son
Female	46-50	Daughter
Male	71-75	Daughter
Male	46-50	Son
Female	46-50	Son
Female	56-60	Daughter
Female	41-45	Husband
Female	61-65	Husband
Oncologists		
Designation	*Years of qualified practice*	*Gender*
Medical oncologist	15	Male
Radiation oncologist	30	Female
Radiation oncologist	6	Male
Surgical oncologist	2	Male
Gynaecology oncologist	35	Female
Surgical oncologist	5	Male
Surgical oncologist	2	Male
Gynaecology oncologist	10	Female
Pulmonologist	10	Female
Surgical oncologist	2	Male

Main findings

In Figure 1 we present the explanatory model generated from the data. In summary, the

model explains how the stigma associated with communicating a diagnosis of advanced

cancer is enacted by treating oncologists, family members and the community. This leads to

patient expectation of cure and uptake of futile treatment. Patients only present needs with

respect to pain and none within psychological, social or spiritual domains, likely due to the

lack of patients' insight into their diagnosis and prognosis. As a result of oncologists' and

families' unwillingness to disclose the prognosis, and patient focus on pain due to their lack

of insight, palliative care clinicians view their services as underutilised, and patients perceive

palliative care simply as a pain management service that is not "different" from other clinical

services. The patient advanced care needs and purchase of futile treatments lead to lost

employment among family members, increased family debt and high care costs, which

family members rarely disclosed to the treatment team due to their unwillingness to discuss

their own needs.

INSERT FIGURE 1 HERE

Communication & understanding

- *Lack of disclosure: clinicians*

Although a range of behaviours were reported by clinicians in terms of disclosure of

diagnosis and prognosis, the common approach was to withhold information from patients,

or to actively give an inaccurate account, perpetuating the stigma of discussing death within

medical and lay discourse.

> *"INTERVIEWER: Do you have patient asking you directly what is wrong with them*
>
> *and so how do you reply?*
>
> *ONCOLOGIST: "At time I will lie. 'I think you are improving or may take some more*
>
> *time', but I know that is not correct, but somehow, we have to balance." [Surgical*
>
> *oncologist]*

To never share accurate information was commonplace,

> *"Interviewer: Is it anytime or numbers of time that you have to actually initiate*
>
> *conversations with patient or their relatives about End of life care?*
>
> *Oncologist: Not actually………It's usually the patient family people ask like how the*
>
> *end is going to come, how patient is going to survive, how long he is going to survive*
>
> *then definitely we explain to them that how the end care will come………If the*
>
> *patients themselves are asking it is very, very rare, for ourselves to explain to them in*
>
> *such a case." [Radiation Oncologist].*

This reluctance to communicate honestly with patients was not restricted to earlier in the

disease trajectory.

> *"INTERVIEWER: Do you actually have an end-of-life conversation?*
>
> *INTERVIEWEE: Not really. Initially, before the recurrence we do not talk.*
>
> *INTERVIEWER: No after the recurrence.*

INTERVIEWEE: No. After the recurrence, also at that point of time, we don't talk about it." [Surgical oncologist].

- *Lack of disclosure: families*

The family is a major driver in non-disclosure to the patient of the stigmatising poor prognosis. Even in cases where the clinician believed the patient should have full information, the family may override this,

"We initially speak to the relatives first, and we do take their input as far as how much to inform the patient first day. But very frankly, in our country, most of the relatives do not want the diagnosis itself to be revealed to the patient, but we always make it a point to mention that the patient has to know, has to understand what is the disease, and what's happening, and the patient has to take the decision as far as therapy or palliative care, whatever the thing, the patient has to be aware. But a very strong, this thing, from the relatives not to tell the patient is put through us, most of the time, but we do make it a point that this is something that the patient has to know, but I do admit that we heed the relatives request not to reveal, or be more open to the patient." [Gynaecological oncologist]

However, some oncologists believed that their patients could manage full disclosure;

"We underestimate the patient's capacity to observe the diagnosis and the treatment and side effects etcetera including the prognosis. So, because as you said the relatives first get to know the diagnosis and then get to know the treatment, prognosis etcetera. There are a lot of uncertainties in the patient's mind as to the diagnosis and the treatment and curability etcetera. So that has to be first addressed so if we involve patient and take him into confidence and before we tell. This happens even in educated patients also. The relatives might be less educated than

the patient, but they take the upper hand, they tell us that the patients cannot take

the shock of the diagnosis etcetera." [Medical Oncologist].

By acquiescing to the family direction not to disclose, many clinicians felt that this led to poorer care later towards the end of life,

"Yeah more than the patient there is some reluctant in part of the relatives. They

think if we discuss from that upfront before the time really has come for that they

think the end is very close. They think that the doctor has given up on the treatment

that treatment is not working so they have lot of apprehensions and negative feeling

associated with those discussions. So, many a time the treating physician is forced to

postpone all this really to the end of the terminally ill stage where the patient may not

be in a real position to take a decision or there are a lot of social thing that go with

the end of life which patient has to be given an opportunity to make decision while he

is in a real state of mind to make those decisions when he is not in real pain, when

he is not disoriented etcetera." [Medical Oncologist].

Even if a clinician attempts to initiate direct communication with the patient, families may physically intervene,

"So many of times we know we face collusions that means our relatives are not

allowing us to say the diagnosis to the patient himself. In fact, they form a physical

barrier if you say right in front of us that, you know, showing us, different gestures

telling us not to tell the right one." [Radiation Oncologist].

Consistent with the oncologists' reports, family members described many instances when they chose to provide untruthful information to the patient regarding their illness, motivated by good intention that the patient may better "fight" the disease if they are unaware of prognosis

"First, we have to develop a feeling in them that we are here to support them. Then

we have to tell them that it is not a severe problem even though it is so, we have to

tell them that if this kind of treatment is taken it will improve her health, or, if there is a

pain, then if she takes a tablet it will be under control. In this way, we fill in courage in

them." [Daughter of hepatocellular cancer patient].

"I convinced him and got him discharged in the morning itself and got him here. The

tests were done here and thought its ulcer and nothing related to cancer. Told him

that it's just ulcer and not cancer and in endoscopy result, we got to know this is

cancer." [Son of stomach cancer patient].

"We had told her this is starting stage but it was 4th stage. She felt bad when we told

its starting stage also" [Son of cervical cancer patient].

- *Lack of disclosure: friends*

Patients and families described feeling stigmatised and socially ostracised from their

community following the onset of illness,

Interviewer: "Your neighbours and the relatives who visit hospitals, have you faced

any trouble from them?

Patient's son: There are changes, since one month their talking and talking behind

our back has changed….....behaviour and all has changed. The way of talking will be

different in front of them and in their back. It was different than before." [Son of

cholangio carcinoma patient]

"Participant: That has become a big problem for us.

Interviewee: Will you tell more about it?

Participant: We have seen many such things. We have seen here also. Nothing has

happened yet. After that only we came to hospital. In my village also no one speaks

properly with us." [Husband of cervical cancer patient].

- *Choosing futile treatment & expecting cure*

Families and clinicians' behaviours regarding communication encouraged patients to pursue

expensive and futile treatment. This exemplifies how the stigma of terminal illness can lead

to adverse financial consequences for the family.

"Patient's daughter: About 3-4 months back, we had shown her once or twice, and

again in 2013 took treatment in Hyderabad, again in Anantpur, Hindupur, Tumkur.

Wherever people say treatment will be given, we have gone there and shown

her…..We have visited about 10 hospitals. We have not got good results, no cure,

even here. Nobody tells correctly about what has happened, what has to be done."
[Son of cervical cancer patient].

"What may be our main issue in our present situation? We have to save our mother.

That is our main issue. What are treatments available and where? Is it here in our

country or is it available in other countries? Is there treatment for this may be it is in

other country? We want to find it out and give it to her and we want to save her. That

is our main concern now." [Daughter of hepatocellular carcinoma cancer patient].

"What to expect, if there was reduction of pain, it would have been good. They won't

tell anything. They told they will put chemotherapy injection. After we said okay for it,

they told that we don't give guarantee for it. One injection is Rs 15000." [Son of

stomach cancer patient].

"I am worried that this got this disease and how much ever we spend money on it,

health is not improving. I am in this condition since 4-5 years and there is no

improvement at all. I am not able to bear the pain". [Female 61-65 year old cervical

cancer patient].

"By next year what I have thought is I have to get up and walk properly. I have to be like all others and walk like others and my disease should be cured. They have given me so much hopes that it will get better. I like to be like a normal person, by getting up and walk normally." [Female 46-50 year old hepatocellular cancer patient].

"I have to eat well if I have to do something related to my health. If I eat I will be fine. I know this 100%." [Female 61-65 *year old* adenocarcinoma patient].

Patient needs

Physical pain was the only concern described by patients and families, and was a major one for both groups. When psychological, social and spiritual needs were probed, none were described. The only social needs were the financial challenges described in relation to pursuing futile treatments (above).

However, the data do suggest that there may be psychological concerns that patients or families choose not to express to families or their clinical team,

"At present, what his feeling is he has to become better and he could be help us more or if he would have listened his wife's advice it would have been better. But anyway, he is not discussing anything openly." [Daughter of lung cancer patient].

This reluctance to share may result from the perceived necessity to focus on cure and active treatment,

"Interviewer: We are talking about your problem. Will you tell your problems to anyone?

Patient: No. I will not tell.

Interviewer: Why you won't tell?

Patient: Why to tell, what the use is by telling others. We only have to get it cured. We have to be quiet keeping this in our stomach, by believing god. If the ways I tell like how I am telling you, they also will spread this to other few by telling she has got big disease. They make the news big. If we eat food it will be inside your stomach, if you drink water it will be inside your stomach. Likewise why you want to tell this. You have to keep this in your stomach and be quiet." [41-45 year old cervical cancer patient].

Family needs

The only self-reported needs among family members were employment and financial ones. The desire to seek costly treatment was described by an oncologist,

"Basically all of them have financial problem if they have money then before this thing end of life I may ask 'do you want to take a second opinion'?" [Surgical oncologist]

Caregiving can also lead to unemployment,

"No problem as such. But the problem was of a job. When I came here to look after, I lost a job. When I came to look after my mother, my job was suspended. Other than this, no other problem. We don't want anything other than the disease getting cured. Now they are telling you need more money. We have got problem for money." [Son of ovarian cancer patient]

As with patients, families chose not to share their distress with others, which suggests that expression of emotional concerns is highly stigmatised

"Interviewer: *Have you ever felt sharing this after seeing him suffer?*

Family member*: I don't like to tell to any relatives as we have to face our own*

difficulties" [Son *of* cervical cancer patient].

Family members described pain management for patients as improving wellbeing of family

members,

"*If pain reduces its good for us. How soon it comes down, it's good for him as well as*

for us" [Wife of adenocarcinoma patient].

Palliative care provision

- *Operates & understood as pain management*

Palliative care was commonly described by oncologists to patients and families as a pain

management service

"*Without telling them that it is palliative care we refer to pain management. We say*

that, that is the pain doctor so you go there and sometimes there are symptoms

which, you know, which we assumed about we tell them to go there, but we don't use

the word palliative care at that time because they still have hope, they think that once

you take palliative care all hope is lost." [Gynaecological oncologist].

"*Interviewer: According to you what is palliative care?*

Patient: Palliative means pain remover.

Interviewer: Is the palliative care that you are taking is different from other cares?

Patient: No, it is not different." [Male 71-75 year old lung cancer patient]

This led to underutilisation of the available trained specialist palliative care team

"*The other problem is the availability of Palliative Care support. In fact, it has to start*

from the diagnosis itself, but then unfortunately most of us are underutilizing

wherever Palliative Care specialists are available also. The services are

underutilized only we are utilizing the services in terminally ill patients, End-of life-

care etcetera or only for pain management. So, it becomes equal to pain

management unfortunately, so that has to change." [Medical Oncologist]

As a result of poor awareness of prognosis, the focus on pain, and the labelling of the

service as pain management, patients do not perceive palliative care as different to their

other care, although it successfully manages pain and optimises function

"This treatment is for the body pain so that she must not experience the body pain.

But this also is helping because pain is the main thing now. If medicines can be taken

at any condition then it is good. If there is pain she cannot do anything. Though she

cannot do her 100%, she can do her 60% work. She can eat, walk, so there is some

use." [Daughter of patient with hepatocellular carcinoma].

This underuse is also evidence in the management to pain, with an example of emergency

room use instead of pre-emptive pain management planning

"If I tell I have small pain, my brother, daughter or son-in-law will rush me to hospital"

[Female 46-50 year old hepatocellular cancer patient]

Lastly, it was recognised that the responsibility for improving palliative care access lies with

the oncologists

"The mindset has to change from the consultant himself. Unfortunately, most of us

are not exposed to Palliative Care why we were doing our super speciality training

itself it starts from there and most of the hospitals including hospital like [hospital

name] don't have good Palliative Care team then we are not put there for training.

During training we have not posted there for long enough to really know the

difference that is made by the Palliative Care especially in the life of the patients and

the relatives especially terminally ill patients. So, it has to start from the specialists

themselves" [Medical Oncologist]

DISCUSSION

This is the first study to determine the role of stigma in advanced cancer in India, integrating

primary data from patients, family members and oncologists. Although there is a literature

identifying this as an area of importance and cultural specificity, this has lacked original data

or an explanatory model of the mechanisms incorporating all potential actors in stigmatising

processes, to inform which interventions might be theoretically plausible and acceptable.

This exploratory study has generated a novel model that identifies the role of stigma in

expressing needs in advanced cancer, communication and disclosure, and in accessing

palliative care. The multilevel model reveals the collusion between clinical teams and

families that leads to pursuit of expensive and futile treatment, poor insight on the part of

patients, and suboptimal use of the wide range of interventions available through palliative

care teams.

Stigma is enacted and perpetuated at all levels, including by clinicians who do not openly

communicate poor prognosis, family members who request this concealment, and by

services that are simply described as "pain management.". Interestingly, no evidence was

found of "opiophobia" among patient and families, only one of whom was aware of morphine.

The data highlight a dissonance between preference and practice, given that the vast

majority of Indian cancer patients prefer to know their diagnosis [17] and the chance of a cure

[20]. Interestingly, our data suggest that patients had problems other than pain, but were

unwilling to share these concerns. We have found previously among advanced cancer

patients in LMIC that poor patient insight regarding diagnosis and prognosis are associated with worse self-reported wellbeing [26], that communicating poor prognosis is a challenge for medical staff in LMIC [27], and that decision-making is likely to be made away from the patient [28].

The results of this study differ somewhat from our previous findings [29-34] on the prevalence and correlates of HIV-related stigma in this region. Stigma enacted by health care providers and family members were driven largely by blame and fear of infection, which led to endorsement of coercive policies, such as mandatory testing and prohibitions on marriage and child-bearing. It also led to unwillingness by both family members and health care staff to care for HIV-infected patients. While no such attitudes were reported in the current study, lack of communication was clearly an issue in the care of both patients diagnosed with HIV and with advanced cancer. Participants in both studies also reported frequent disease-related misconceptions and an unwillingness to discuss sensitive topics, such as a poor prognosis and, in both cases, family members appeared to feel shame over the diagnosis of their loved one. In both situations, this shame, together with misconceptions regarding the disease, fear and lack of communication likely drove stigma and led to sub-optimal treatment.

There are a number of limitations to this exploratory study. Firstly, we did not aim to collect data on the content of the clinical encounter and therefore it may be that oncologists share information but this is poorly understood. However, our data from oncologists and family members strongly contradict that possibility, as they describe requests to conceal information. Secondly, our data were only collected in one private, non-profit Indian medical college hospital and we strongly recommend the expansion of this model through primary data collection in other types of institutions and multiple parts of India. Third, there may have been both a sampling and participation bias in that those with insight but a poor reaction to the information may not have consented to participate. We are not aware of any conflicts of interest in this study.

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Previous studies form Pacific Asia have found that, despite popular belief, people would prefer to be given full information regarding diagnosis and prognosis [35-38]. Lack of disclosure of prognosis and introduction to the goals of palliative care in this population may have an interesting outcome, in that patients are more willing to be referred to palliative care when it is described as "pain management". However, this must be very carefully balanced against the poor outcomes described- pursuit and payment of futile treatments, lack of disclosure of concerns, very low levels of insight, and clinician views of under-use of the range of care and support available through palliative care staff.

There is evidence from the field of HIV in India that stigma-reducing interventions are wanted, feasible and acceptable[39-41] .We have a number of recommendations from our findings that aim to improve access to palliative and end-of-life care for patients and families affected by advanced cancer in India. Firstly, in order for patients and families to claim their right to affordable palliative care under the Universal Health Coverage, oncologists and families must enact the right to information about diagnosis and prognosis. However, this has to be done in a feasible and acceptable way and not unduly add to distress. This requires an intervention that supports families to accept and share poor prognosis with the patient and community. Second, to enable this right to information, oncologists require interventions that can enable them to handle these difficult, ongoing conversations in a way that is acceptable to families. In the context of concealed prognosis and pursuit of futile treatment, information giving must be seen as a process and not a single event. Third, building on our first two recommendations, the intervention must focus on the central information gatekeeping role of the family, who are likely to make key decisions and to act as physical and emotional barriers to information sharing between the oncologist and patient. In high-income countries there is evidence to suggest that family meetings may enhance family-patient-team communication[42]. Fourth, our data suggests that patients conceal their concerns. Within the model this appears to be driven to the stigma surrounding diagnosis

and poor prognosis that is enacted by collusion between clinicians and families, keeping the patient's focus upon cure and recovery. Intervention must empower patients to share their concerns beyond physical pain, to the extent that they wish by reducing perceived or internalised stigma. This will require oncology and palliative care services to use terminology that identifies palliative care as being more than simply a physical pain service, and enabling families to hear patient distress. Fifth, interventions must be developed from an expanded theory of stigma in advanced cancer, refining our model from the exploratory data using data from a wider geographical sample of oncologists, patients and families in India.

Our novel theoretical model is an essential first step to ensure that any proposed complex intervention is plausible and has a proposed mechanism of action that addresses all relevant stakeholder populations. Taking a family-centred approach, with an oncology workforce skilled in communication and an enabled patient population may be feasible and acceptable. Through this, improved access to palliative care with improved outcomes may be attainable.

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CONTRIBUTOR STATEMENT

The study was conceived by ME SN and RH, SN was local PI and analysis was led by RH with ME and SN reviewing and agreeing the data coding frame. The interpretation of findings was jointly by RH, SN and ME, and all authors contributed to and approved the final

manuscript. RH led the drafting of the manuscript with contribution and by all authors and final approval by all authors.

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DATA SHARING STATEMENT

The raw data (transcripts) are available from the corresponding author upon reasonable request by email.

COMPETING INTERESTS STATEMENT

The authors have no competing interests to declare.

Figure 1 Explanatory model of the data

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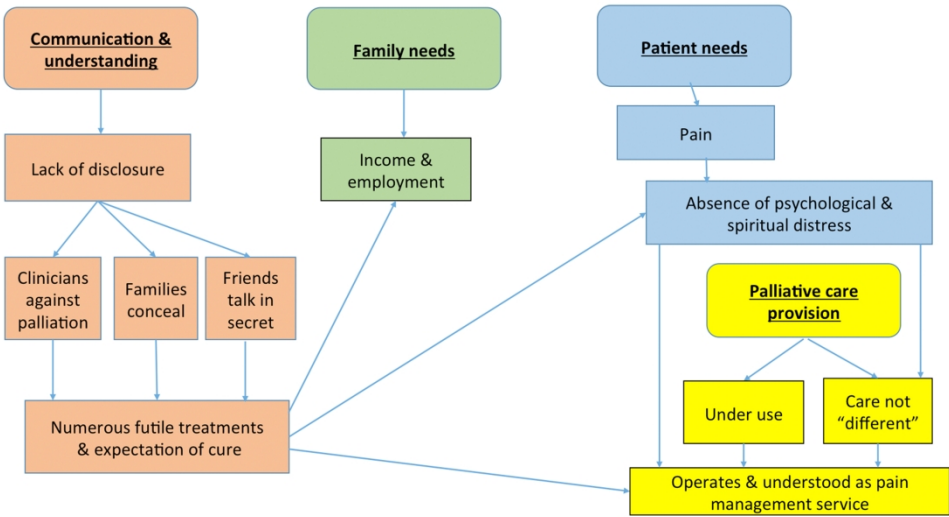51
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Figure 1 Explanatory model of the data

595x334mm (300 x 300 DPI)

SRQR Checklist HARDING

bmjopen-2018-024248 entitled "A multilevel model of stigma and barriers to cancer palliative care in India: a qualitative study."

SRQR number	Item	Met?
Title and abstract		
S1	Title Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	✓
S2	Abstract Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	✓
S3	Problem formulation Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	✓
S4	Purpose or research question Purpose of the study and specific objectives or questions	✓
Introduction		
S5	Qualitative approach and research paradigm Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale	✓
S6	Researcher characteristics and reflexivity Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	✓
S7	Context Setting/site and salient contextual factors; rationale.	✓
S8	Sampling strategy How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale	✓
S9	Ethical issues pertaining to human subjects Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	✓
S10	Data collection methods Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis,	✓

		iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale	
S11	Data collection instruments and technologies Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	✓
S12	Units of study number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	✓
S13	Data processing Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/ deidentification of excerpts	✓
S14	Data analysis Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually	✓
S15	Techniques to enhance trustworthiness Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale.	✓
Results			
S16	Synthesis and interpretation Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	✓
S17	Links to empirical data Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	✓
Discussion			
S18	Integration with prior work, implications, transferability, and contribution(s) to the field. Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field.	✓
S19	Limitations Trustworthiness and limitations of findings	✓
S20	Conflicts of interest Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	✓
S21	Funding Sources of funding and other support; role of funders in data collection, interpretation, and reporting	✓