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Sengar, Manju; Fundytus, Adam; Hopman, Wilma; Pramesh, C S; Radhakrishnan, Venkatraman; Ganesan, Prasanth; Mathew, Aju; Lombe, Dorothy; Jalink, Matthew; Gyawali, Bishal

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Cancer Medicines: What Is Essential and Affordable in India?

Manju Sengar, MD¹; Adam Fundytus, MD^{2,3}; Wilma Hopman, MA⁴; C.S. Pramesh, MS⁵; Venkatraman Radhakrishnan, MD⁶; Prasanth Ganesan, MD⁷; Aju Mathew, MD⁸; Dorothy Lombe, MD⁹; Matthew Jalink, MSc^{2,4}; Bishal Gyawali, MD^{2,3,4}; Dario Trapani, MD¹⁰; Felipe Roitberg, MD¹¹; Elisabeth G.E. De Vries, MD¹²; Lorenzo Moja, MD¹³; André Ilbawi, MD¹³; Richard Sullivan, PhD¹⁴; and Christopher M. Booth, MD^{2,3,4}

PURPOSE The WHO essential medicines list (EML) guides selection of drugs for national formularies. Here, we evaluate which medicines are considered highest priority by Indian oncologists and the extent to which they are available in routine practice.

METHODS This is a secondary analysis of an electronic survey developed by the WHO EML Cancer Medicine Working Group. The survey was distributed globally using a hierarchical snowball method to physicians who prescribe systemic anticancer therapy. The survey captured the 10 medicines oncologists considered highest priority for population health and their availability in routine practice.

RESULTS The global study cohort included 948 respondents from 82 countries; 98 were from India and 67 were from other low- and middle-income countries. Compared with other low- and middle-income countries, the Indian cohort was more likely to be medical oncologist (70% v 31%, $P < .001$) and work exclusively in the private health system (52% v 17%, $P < .001$). 14/20 most commonly selected medicines were conventional cytotoxic drugs. Universal access to these medicines was reported by a minority of oncologists; risks of significant out-of-pocket expenditures for each medicine were reported by 19%-58% of oncologists. Risk of catastrophic expenditure was reported by 58%-67% of oncologists for rituximab and trastuzumab. Risks of financial toxicity were substantially higher within the private health system compared with the public system.

CONCLUSION Most high-priority cancer medicines identified by Indian oncologists are generic chemotherapy agents that provide substantial improvements in survival and are already included in WHO EML. Access to these treatments remains limited by major financial burdens experienced by patients. This is particularly acute within the private health system. Strategies are urgently needed to ensure that high-quality cancer care is affordable and accessible to all patients in India.

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BACKGROUND

Advances in systemic therapy have led to improved survival in many cancers. However, there is a wide range in the magnitude of benefit associated with these advances.^{1,2} Translating these gains from clinical trials into improved outcomes in the real world is contingent on the medicines being accessible and affordable. These newer therapies are very expensive, often disproportionate to the gains in survival.³⁻⁵ Procurement of these medicines strain budgets in all health systems but most acutely in low- and middle-income countries (LMICs) such as India. Most low-resource health systems do not include expensive cancer medicines in their public reimbursement schemes, thereby putting patients at risk of significant out-of-pocket (OOP) or catastrophic expenditure. This calls for a careful assessment of anticancer systemic therapy before their inclusion in national formularies. The WHO essential medicines list (EML) is

developed through a systematic appraisal of evidence on the magnitude of benefit, safety, and feasibility of delivery across diverse health systems.⁶ The EML provides much-needed guidance for policymakers tasked with the prioritization and procurement of medicines.⁷ Over the years, the WHO EML has grown from seven cancer medicines in 1977 to 59 in 2021, reflecting the development of new highly effective therapeutic options in the field, increasing burden of cancer and WHO's response to cancer prevention and control.^{6,8,9}

The public health burden of cancer in India is growing steadily, with a projected cancer incidence of 1.4 million cases in the year 2020.¹⁰ More than 80% of these patients present with advanced-stage disease because of awareness, access, and affordability challenges.¹¹ This translates into a higher need for effective and affordable systemic anticancer therapy options and palliative care. The National List of

ASSOCIATED CONTENT

Appendix

Data Supplement

Author affiliations and support information (if applicable) appear at the end of this article.

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CONTEXT

Key Objective

To understand which cancer medicines are considered most important by Indian oncologists and the extent to which they are available in routine clinical practice.

Knowledge Generated

The majority of high-priority medicines selected by Indian oncologists are older generic chemotherapy and hormone medicines. All the medicines selected by the Indian oncologists are already included in the WHO-essential medicines list and India's National List of Essential Medicine. Access to these high-priority off-patent drugs continues to result in significant out-of-pocket or catastrophic expenditure; this is most pressing in the private sector.

Relevance

The findings from this study highlight the need to strengthen existing systems for pricing, quality monitoring, and procurement to promote the universal access for essential medicines.

Essential Medicine (NLEM) in India was established in 1996 and has undergone periodic revisions since then.¹² The NLEM is based on the same principles as WHO EML complemented by relevant local information such as country-specific disease patterns and locally approved drugs. Inclusion of a drug in NLEM ensures price control as per the Drug Price Control Order Act and thus can improve affordability and access.¹³

Our group has recently reported the results of an international survey among oncologists from 82 countries to understand the extent to which the EML reflects high-priority medicines of clinicians and whether these drugs are accessible on the frontlines of care.¹⁴ The study showed substantial convergence between the EML and medicines that clinicians prioritize. However, the study illustrated striking financial barriers to accessing these medicines in routine care, especially in LMICs and upper-middle-income countries (UMICs).

Cancer care delivery in India is unique in terms of mix of private and public sector facilities.¹⁵ Cancer care in the public system is supported through government-funded schemes to a certain extent, whereas care in the private sector is largely financed through OOP expenditure, with trivial proportion being covered by private insurances or reimbursement from employers. Approximately 60%-75% of patients with cancer in India receive care in private health care facilities and are thus subject to the risk of significant OOP expenditure and distressed financing.¹⁵ Moreover, even within the public system, payment schemes may not cover the full cost of medicines and their availability can be erratic, leading to OOP expenditures for patients who have to obtain medicines elsewhere. This model of health care coupled with wide income inequalities in the country brings considerable challenges for access and affordability of anticancer drugs. Given the unique features of India's health system, we undertook a secondary analysis of the primary global cohort to understand which medicines are considered most relevant by physicians in India and the extent to which they are accessible and affordable on the frontlines of care.

METHODS

Study Population

The current report is a secondary analysis of the global study recently reported elsewhere.¹⁴ The study concept was developed by investigators with expertise in research methodology, health policy, global health, and clinical cancer care in close conjunction with the activities of the WHO Essential Medicines Cancer Working Group, which supports the identification and evaluation of cancer medicines for inclusion on the WHO Model List. The study population for this cross-sectional survey included fully qualified physicians who deliver systemic anticancer therapy. Physicians who treat only children were excluded as they were part of a similar survey being done for pediatric cancers.

Survey Design and Distribution

The original survey was developed using Qualtrics online survey platform.¹⁶ Pilot testing was performed by the study team and 10 additional oncologists from diverse global settings. The final survey consisted of 28 questions and took 8-10 minutes to complete (Data Supplement). The survey was only available in English and responses remained anonymous. The study was approved by the Research Ethics Board at Queen's University.

The primary survey question asked "Imagine your government has put you in charge of selecting anticancer medicines for your country. You are only allowed to select a maximum of 10 medicines that will be available to treat all cancers in your country. Which drugs would you recommend to the government to achieve the greatest benefit for the most patients? Assume that cost (system and patient) is not an issue and that you have access to the necessary supportive care medicines, diagnostic, and laboratory services." The survey allowed respondents to select up to 10 drugs from an expansive list of 164 anticancer drugs approved by Health Canada as of September 2020.¹⁷ Out of these 164 anticancer drugs, 138 are approved in India (Appendix Table A1).

TABLE 1. Demographics and Clinical Practice Setting of Respondents to Global Cancer Essential Medicines List Survey Stratified by World Bank Economic Classification

Characteristic	India (n = 98) No. (%)	LMICs (n = 67) ^a No. (%)	UMICs (n = 165) No. (%)	HICs (n = 618) No. (%)	P
Demographics ^b					
Sex, No. (%)					
Male	67 (86)	34 (59)	94 (66)	349 (64)	.001
Female	11 (14)	24 (41)	48 (34)	198 (36)	
Mean age, years (SD)	42 (9)	46 (9)	48 (11)	47 (10)	< .001 ^c
Mean years in practice (SD)	11 (10)	12 (8)	15 (12)	14 (10)	.018 ^d
Clinical practice ^b					
Specialty, No. (%)					
Medical Oncology	69 (70)	21 (31)	110 (67)	514 (83)	< .001
Radiation Oncology	12 (12)	5 (8)	2 (1)	7 (1)	
Clinical Oncology	11 (11)	35 (52)	51 (31)	62 (10)	
Other	6 (6)	6 (9)	2 (1)	35 (6)	
Health system, No. (%)					
Public	28 (35)	23 (40)	38 (26)	385 (70)	< .001
Private	41 (52)	10 (17)	59 (41)	98 (18)	
Both	10 (13)	25 (43)	47 (33)	64 (12)	
Location, No. (%)					
Urban	67 (85)	50 (86)	133 (92)	481 (88)	.176
Rural	4 (5)	5 (9)	1 (1)	23 (4)	
Both	8 (10)	3 (5)	10 (7)	43 (8)	
Types of cancer treated, No. (%)					
Solid	25 (32)	27 (47)	119 (83)	441 (81)	< .001
Hematologic	7 (9)	2 (3)	3 (2)	43 (8)	
Both	46 (59)	29 (50)	22 (15)	63 (12)	
Academic center, No. (%)					
Yes	61 (78)	46 (81)	90 (63)	383 (70)	.023
No	17 (22)	11 (19)	54 (38)	164 (30)	
Base of practice, No. (%)					
Hospital-based	66 (85)	47 (81)	94 (65)	507 (93)	< .001
Clinic-based	1 (1)	1 (2)	20 (14)	18 (3)	
Both	11 (14)	10 (17)	30 (21)	21 (4)	
No. of cancer sites treated, %					
1	9 (12)	5 (9)	10 (7)	194 (36)	< .001
2	3 (4)	2 (3)	8 (6)	86 (16)	
3+	66 (85)	51 (88)	126 (88)	267 (49)	
Type of therapy, No. (%)					
Systemic	74 (75)	26 (39)	137 (83)	566 (92)	< .001
Both systemic and radiation	24 (25)	41 (61)	28 (17)	52 (8)	
Treat children/adults, No. (%)					
Adults only	29 (30)	39 (58)	155 (94)	604 (98)	< .001
Adults and children	69 (70)	28 (42)	10 (6)	14 (2)	

Abbreviations: HICs, high-income countries; LMICs, low- and middle-income countries; SD, standard deviation; UMICs, upper-middle-income countries.

^aLMIC numbers exclude India.

^bThirteen were missing much of these data since they did not complete the entire survey (121 number of cancer sites, 123 sex/gender, 120 health system, 120 location, 121 types of cancer, 122 academic center, 122 base of practice, 405 years in practice, and 126 age; hence, the denominator can change depending on the variable). The chi-square percentages are based on the subset with responses, as are the *P* values.

^cLMICs did not differ from the others; UMICs differed from India (*P* < .001); HICs differed from India (*P* < .001), Tukey's post hoc tests.

^dLMICs did not differ from the others; UMICs differed from India (*P* = .038); HICs differed from India (*P* = .045), Tukey's post hoc tests.

The second set of questions related to the access of each selected drug by eligible patients in the routine clinical practice setting of the participant. A scale was developed on the basis of prior work by the European Society for Medical Oncology with modifications to explicitly identify the risks of significant and catastrophic expenditure.¹⁸⁻²⁰ The scale included four categories: (1) universally accessible (no significant OOP expenses for > 90% of patients); (2) accessible with significant OOP expenses (mixed/partial reimbursement model and not universal health coverage); (3) accessible with high-risk of catastrophic expenditure (significant OOP for > 50% of patients with substantial risk of catastrophic health expenditure defined as spending that absorbs more than 40% of total consumption, net of food expenditures); and (4) unavailable for other reasons (ie, procurement and regulatory).

The primary study population was enrolled from a global network of oncologists. This sampling frame was derived from two sources: (1) membership of national/regional oncology organizations and (2) personal networks of a single oncologist contact in countries where national organizations did not exist or were unable to distribute the survey.

Distribution of the web survey used a hierarchical snowball method through a primary global network composed of oncologist contacts in 89 distinct countries/regions. This method was used earlier for a global study addressing oncologists' workload.²¹ The survey was open during October 15-December 7, 2020. After the initial distribution, one reminder was sent to each country/regional contact. In India, the survey was distributed through the mailing list of the National Cancer Grid, which is a network of more than 250 cancer centers, research organizations, and patient groups,²² and through the personal network of medical oncologists using WhatsApp and e-mails.

Statistical Analysis

Survey responses were downloaded into IBM SPSS (version 27.0 for Windows, Armonk, NY, 2020). Participants were classified into three groups on the basis of World Bank income status of their country of practice: LMICs, UMICs, and high-income countries (HICs).²³ Respondents who did not complete the primary survey question (listing of top 10 medicines) were deemed incomplete and excluded. Missing data for demographic variables and access to medicines were identified in the Appendix [Table A2](#)

TABLE 2. The 20 Most Commonly Selected Medicines by 948 Oncologists in Response to the Question “Which Cancer Drugs Would You Want for Your Country to Achieve the Greatest Public Health Benefit?” (assume cost is not an issue, maximum 10 drugs)

Top 20 India (n = 98)	No. (%)	Top 20 LMICs^a (n = 67)	No. (%)	Top 20 UMICs (n = 165)	No. (%)	Top 20 HICs (n = 618)	No. (%)
Doxorubicin	57 (58)	Doxorubicin	48 (72)	Doxorubicin	94 (57)	Pembrolizumab	311 (50)
Cisplatin	52 (53)	Cisplatin	39 (58)	Pembrolizumab	86 (52)	Doxorubicin	300 (49)
Cyclophosphamide	51 (52)	Cyclophosphamide	39 (58)	Trastuzumab	84 (51)	Cisplatin	300 (49)
Carboplatin	46 (47)	Carboplatin	38 (57)	Cisplatin	79 (48)	FU	277 (45)
Capecitabine	45 (46)	Paclitaxel	36 (54)	Carboplatin	72 (44)	Paclitaxel	276 (45)
Paclitaxel	43 (44)	Capecitabine	35 (52)	Paclitaxel	68 (41)	Trastuzumab	275 (44)
Imatinib	34 (35)	Tamoxifen	31 (46)	Tamoxifen	67 (41)	Carboplatin	234 (38)
Docetaxel	32 (33)	FU	30 (45)	Capecitabine	64 (39)	Tamoxifen	228 (37)
Trastuzumab	29 (30)	Oxaliplatin	25 (37)	FU	60 (36)	Capecitabine	185 (30)
Methotrexate	27 (28)	Docetaxel	24 (36)	Docetaxel	57 (35)	Oxaliplatin	184 (30)
Rituximab	26 (27)	Gemcitabine	22 (33)	Cyclophosphamide	51 (31)	Docetaxel	183 (30)
Gemcitabine	23 (23)	Dexamethasone	20 (30)	Oxaliplatin	48 (29)	Dexamethasone	182 (29)
Bortezomib	23 (23)	Vincristine	18 (27)	Abiraterone	41 (25)	Cyclophosphamide	177 (29)
Vincristine	22 (22)	Etoposide	17 (25)	Anastrozole	31 (19)	Nivolumab	173 (28)
Dexamethasone	21 (21)	Trastuzumab	14 (21)	Osimertinib	29 (18)	Rituximab	146 (24)
Gefitinib	21 (21)	Methotrexate	13 (19)	Imatinib	28 (17)	Osimertinib	112 (18)
Tamoxifen	19 (19)	Imatinib	11 (16)	Goserelin	27 (16)	Imatinib	111 (18)
FU	19 (19)	Bleomycin	9 (13)	Gemcitabine	26 (16)	Letrozole	111 (18)
Etoposide	19 (19)	Rituximab	9 (13)	Dexamethasone	25 (15)	Gemcitabine	109 (18)
Cytarabine	18 (18)	Leucovorin	8 (12)	Etoposide	25 (15)	Etoposide	109 (18)

NOTE. Overall results are shown for all respondents in addition to rank order lists for three different World Bank economic classifications on the basis of respondents' country of practice, and India. Bolded medicines are not included in the current WHO essential medicines list.

Abbreviations: FU, fluorouracil; HICs, high-income countries; LMICs, low- and middle-income countries; UMICs, upper-middle-income countries.

^aLMICs, with India excluded.

footnotes; percentages were calculated on the basis of those who did provide a response. Frequency tables were derived for rank order of medications that respondents listed as most essential. The demographic data and clinical practice setting details of the respondents from India were compared with 18 other LMICs (excluding India). A comparison for access to these drugs was done between oncologists working in private health systems and those who work in public health systems or both.

Demographics and clinical practice setting were compared with Pearson chi-square or the Fisher's exact test for categorical data, and the one-way analysis of variance adjusted with Tukey's post hoc tests for multiple comparisons for age and years in practice. A P of $< .05$ was used as the cutpoint for statistical significance, and no additional adjustment for multiple comparisons was made.

RESULTS

The global study cohort included 948 respondents from 82 countries (after excluding 423 who did not answer the primary study question and 326 who were ineligible as they were trainees or did not prescribe chemotherapy). Median survey response rate for the global population was 6%; the response rate for India was unknown as the number of oncologists who received the survey was not measurable.

Among the 948 respondents, 618 (65%) were from HICs, 165 (17%) from UMICs, 67 (7%) from other LMICs, and 98 (10%) from India (Table 1). Eighty-six percent of respondents from India were males; this was substantially higher than other LMICs (59%), UMICs (66%), and HICs (64%; $P < .001$). Medical oncologists constituted 70% of the respondents from India but only 31% in other LMICs (where there were a higher proportion of clinical oncologists [$P < .001$]). Fifty-two percent of the respondents from

TABLE 3. Access to the 20 Most Frequently Selected High-Priority Medicines Identified by 98 Oncologists From India

Drug Name	No. ^a	Universally Available, ^b No. (%)	Significant OOP Expenses, ^c No. (%)	Risk of Catastrophic Expenditure, ^d No. (%)	
				Not Available, No. (%)	
Doxorubicin	56	24 (43)	22 (39)	10 (18)	0 (0)
Cisplatin	49	31 (63)	14 (29)	4 (8)	0 (0)
Cyclophosphamide	50	25 (50)	17 (34)	8 (16)	0 (0)
Carboplatin	44	18 (41)	19 (43)	7 (16)	0 (0)
Capecitabine	42	12 (29)	18 (43)	10 (24)	2 (5)
Paclitaxel	40	13 (33)	23 (58)	4 (10)	0 (0)
Imatinib	31	10 (32)	17 (55)	4 (13)	0 (0)
Docetaxel	31	7 (23)	18 (58)	6 (19)	0 (0)
Trastuzumab	27	3 (11)	6 (22)	18 (67)	0 (0)
Methotrexate	25	11 (44)	11 (44)	2 (8)	1 (4)
Rituximab	26	3 (12)	8 (31)	15 (58)	0 (0)
Gemcitabine	22	3 (14)	12 (55)	5 (23)	2 (9)
Bortezomib	23	6 (26)	11 (48)	6 (26)	0 (0)
Vincristine	21	12 (57)	5 (24)	4 (19)	0 (0)
Dexamethasone	21	15 (71)	4 (19)	2 (10)	0 (0)
Gefitinib	20	8 (40)	10 (50)	2 (10)	0 (0)
Tamoxifen	17	8 (47)	8 (47)	1 (6)	0 (0)
FU	18	10 (56)	7 (39)	1 (6)	0 (0)
Etoposide	18	10 (56)	5 (28)	2 (11)	1 (6)
Cytarabine	18	6 (33)	7 (39)	5 (28)	0 (0)

NOTE. Percentages may exceed 100 because of rounding.

Abbreviations: FU, fluorouracil; OOP, out-of-pocket.

^aResponses do not equal the number who selected the drug since many respondents made their drug selections and exited the survey; the number responding is provided in column 2.

^bAvailable for all patients with no significant out-of-pocket expenses for more than 90% of patients (ie, universal health care coverage).

^cAvailable for all patients with significant OOP expenses for some patients, on the basis of the health insurance schemes (mixed model, not universal health care coverage).

^dNot universal health care coverage, substantial risk of catastrophic health expenditure. Catastrophic expenditure defined as expenditure that absorbs more than 40% of total consumption, net of an allowance for food expenditures.

India worked exclusively in private health systems. This was substantially higher than other LMICs (17%), UMICs (41%), and HICs (18%; $P < .001$).

Compared with oncologists in UMICs and HICs, those from India and other LMICs were more likely to treat both solid and hematologic tumors (UMICs 15%, HICs 12%, India 59%, and other LMICs 50%; $P < .001$). Seventy percent of oncologists from India treated both adults and children, which was higher than those from other LMICs (42%), UMICs (6%), and HICs (2%; $P < .001$).

Table 2 shows the top 20 anticancer drugs selected by the respondents. All the top 20 medicines selected by Indian physicians are currently included in the WHO EML. The majority of highest-priority medicines were conventional cytotoxic therapy (14/20); 5/20 were targeted therapy, and 1/20 was hormonal therapy. There was substantial convergence between the top 20 list from India and other

LMICs (17/20 medicines are identical). Lack of convergence was seen for bortezomib, gefitinib, and cytarabine (on India's list), and oxaliplatin, bleomycin, and leucovorin (on other LMICs list). It is notable that the top 20 lists from India and other LMICs did not include immunotherapy drugs or newer-generation hormones; pembrolizumab, nivolumab, letrozole, and anastrozole were included in lists from higher-income countries.

Access to the 20 highest-priority medicines in India is shown in Table 3. Significant OOP expenditure for conventional cytotoxic therapy was reported by 19%-58% of oncologists from India. Catastrophic expenditure was reported by more than 20% of oncologists for six drugs, three of which are well-established cytotoxic drugs (capecitabine, gemcitabine, and cytarabine). Access to rituximab and trastuzumab was most challenging, with 58% and 67% of oncologists reporting risks of catastrophic expenditure,

TABLE 4. Access to the 20 Most Frequently Selected High-Priority Medicines Identified by 98 Oncologists From India, Stratified by Working in Public (n = 38)^a or Private (n = 48) Health Systems

Drug Name	No. ^b		Universally Available, ^c No. (%)		Significant OOP Expenses, ^d No. (%)		Risk of Catastrophic Expenditure, ^e No. (%)		Not Available, No. (%)	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
Doxorubicin	18	28	9 (50)	10 (36)	9 (50)	10 (36)	0 (0)	8 (29)	0 (0)	0 (0)
Cisplatin	21	20	16 (76)	10 (50)	5 (24)	7 (35)	0 (0)	3 (15)	0 (0)	0 (0)
Cyclophosphamide	21	21	12 (57)	10 (48)	9 (43)	6 (29)	0 (0)	5 (24)	0 (0)	0 (0)
Carboplatin	18	21	10 (56)	5 (24)	8 (44)	10 (48)	0 (0)	6 (29)	0 (0)	0 (0)
Capecitabine	14	21	7 (50)	3 (14)	4 (29)	10 (48)	1 (7)	8 (38)	2 (14)	0 (0)
Paclitaxel	20	18	11 (55)	1 (6)	9 (45)	14 (78)	0 (0)	3 (17)	0 (0)	0 (0)
Imatinib	13	15	6 (46)	4 (27)	6 (46)	10 (67)	1 (8)	1 (7)	0 (0)	0 (0)
Docetaxel	11	16	6 (55)	1 (6)	4 (36)	10 (63)	1 (9)	5 (31)	0 (0)	0 (0)
Trastuzumab	9	13	3 (33)	0 (0)	1 (11)	3 (23)	5 (56)	10 (77)	0 (0)	0 (0)
Methotrexate	14	7	6 (43)	3 (43)	7 (50)	3 (43)	0 (0)	1 (14)	1 (7)	0 (0)
Rituximab	14	7	2 (14)	1 (14)	4 (29)	2 (29)	8 (57)	4 (57)	0 (0)	0 (0)
Gemcitabine	9	7	1 (11)	0 (0)	5 (56)	4 (57)	1 (11)	3 (43)	2 (22)	0 (0)
Bortezomib	6	13	4 (67)	1 (8)	2 (33)	8 (62)	0 (0)	4 (31)	0 (0)	0 (0)
Vincristine	11	8	8 (73)	3 (38)	2 (18)	3 (38)	1 (9)	2 (25)	0 (0)	0 (0)
Dexamethasone	7	13	6 (86)	8 (62)	1 (14)	3 (23)	0 (0)	2 (15)	0 (0)	0 (0)
Gefitinib	10	8	5 (50)	2 (25)	4 (40)	5 (63)	1 (10)	1 (13)	0 (0)	0 (0)
Tamoxifen	11	6	5 (46)	3 (50)	6 (55)	2 (33)	0 (0)	1 (17)	0 (0)	0 (0)
FU	7	7	4 (57)	3 (43)	3 (43)	3 (43)	0 (0)	1 (14)	0 (0)	0 (0)
Etoposide	8	9	5 (63)	4 (44)	2 (25)	3 (33)	0 (0)	2 (22)	1 (13)	0 (0)
Cytarabine	3	11	2 (67)	2 (18)	1 (33)	5 (46)	0 (0)	4 (36)	0 (0)	0 (0)

Abbreviations: FU, fluorouracil; OOP, out-of-pocket.

^aPhysicians who practice in public and private (n = 10) were classified as public. Twelve of 98 Indian physicians did not report the health system in which they worked.

^bThe number who provided a response is shown in columns 2 and 3.

^cAvailable for all patients with no significant out-of-pocket expenses for more than 90% of patients (ie, universal health care coverage).

^dAvailable for all patients with significant OOP expenses for some patients, on the basis of the health insurance schemes (mixed model, not universal health care coverage).

^eNot universal health care coverage, substantial risk of catastrophic health expenditure. Catastrophic expenditure defined as expenditure that absorbs more than 40% of total consumption, net of an allowance for food expenditures.

respectively. These results are comparable with access reported by oncologists in other LMICs (Appendix Table A2).

The results stratified by practice setting of oncologists in India (exclusively private v public ± private health sector) are shown in Table 4. The proportion of oncologists who report universal access to high-priority medicines is much higher in the public system. The risk of financial toxicity is substantially higher in the private system, where 23%-78% of oncologists reported each drug being associated with significant OOP expenditure. Catastrophic expenditure was reported by more than 20% of oncologists from private health care systems for 13 drugs, including 10 conventional cytotoxic drugs. Access to trastuzumab, rituximab, and bortezomib was limited by risks of catastrophic expenditure as reported by 77%, 57%, and 31% of private sector oncologists, respectively.

DISCUSSION

Our study offers important insight into the cancer medicines considered highest priority in the Indian context and the extent to which they are affordable. The most critical finding of the current study is the lack of universal access to these essential medicines in India. This places considerable economic burden on patients while undergoing cancer treatment; this is felt most acutely by the most vulnerable populations. This has important implications for Indian health policy, particularly for progressive universalism for social coverage of systemic therapies.

The results of this study also highlight the fact that the majority of recent blockbuster medicines in oncology are not considered high priority by oncologists in India. This is likely because of the small incremental gains offered by most new medicines and the fact that many are only effective in small subgroups of patients.³ Our study identifies those medicines that offer the greatest patient- and population-level benefit in terms of survival gains; these agents should be the target of policy actions, including being prioritized for reimbursement by health care systems.

All of the top 20 highest-priority medicines selected by Indian oncologists are already included on the WHO EML and NLEM of India. Well-established cytotoxic drugs, mostly discovered in the 20th century and exposed to global generic competition in the past 10-20 years (eg, doxorubicin, cyclophosphamide, paclitaxel, carboplatin, methotrexate, cytarabine, capecitabine, fluorouracil, and gemcitabine), dominated the list. Universal access for these old and inexpensive conventional chemotherapy drugs was reported by < 50% of Indian oncologists. Significant OOP expenditure for some of these older drugs that are essential components of treatment regimens for common curable cancers in India can have a significant detrimental effect. The use of targeted therapies such as rituximab and trastuzumab, which have shown remarkable benefits in survival, would lead to catastrophic expenditure as reported by more than 50% of oncologists and therefore cannot be used

for all eligible patients. These challenges were even more pronounced within the private sector. The risk of catastrophic expenditure was reported by 7%-77% of private-sector oncologists for all the medicines in the list. These barriers exist despite the fact that India has multiple generic and biosimilar options for the top 20 priority medicines that should promote competition and lower prices.²⁴

The National Pharmaceutical Pricing Authority has set a ceiling price for the medicines listed in NLEM (drug pricing control order).¹³ Several government-funded programs including the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (a large government-funded insurance scheme covering the poorest 40% of India's population) were created to support treatment of the marginalized segment of society within the public health system.^{25,26} Notably, all the high-priority drugs identified by oncologists in our survey are covered by this scheme; however, frequent stockouts and concerns about drug quality often force patients to obtain their own supply. Although these measures likely reduce financial toxicity in the public system, major problems still exist in the private sector, where most Indian patients access health care.¹⁵ Price control has led to many innovators moving out of the market in India and limited suppliers with variable quality bidding for cancer medicine tenders within the public health system. Lack of systems to ensure stringent credential checks and inability to sustain production of drugs at the price-controlled costs lead to supply chain management failures, resulting in frequent stockouts and concerns about drug quality. This leads to patients buying these drugs from outside the public hospitals with significant expenditures. The process of procurement and sale of the drugs in the private sector remains largely unregulated and contributes to significant OOP and catastrophic expenditure.^{27,28} Further work is needed to better understand the medicine supply chain and identify the steps leading to prices becoming unaffordable for patients.

TABLE 5. Recommendations to Improve Access and Affordability to High-Priority Cancer Medicines in India

Recommendations
Establish fair prices to allow manufacturers to sustain production, supply-chain management, and innovation while also ensuring medicines are affordable and accessible
Develop indicators and stringent regulations for drug quality coupled with continuous quality monitoring of generics through random audits
Group negotiation and pooled procurement of high-priority cancer medicines for all the public and private health facilities to enable significant price discounts
Implement systems to monitor the sale, stockouts, and prices paid by patients for cancer medicines
Mandatory health technology assessment (including explicit consideration of the magnitude of clinical benefit) before inclusion of new cancer medicines in the NLEMs

Abbreviation: NLEM, National List of Essential Medicine.

The priority list of oncologists from India had 85% concordance with that of other LMICs, highlighting the wide consensus on relevance of these drugs in similar settings. Notably, immunotherapy drugs such as pembrolizumab and nivolumab were not identified as high-priority medicine by Indian physicians (but were selected by oncologists in UMICs and HICs). Similarly, gefitinib was selected instead of osimertinib.²⁹ Accordingly, although the survey explicitly asked respondents not to consider cost, it is possible that Indian oncologists remained mindful of the potential cost implications associated with these medicines, especially in light of the fact that many of the older and generic medicines remain unaffordable for patients in their day-to-day practice. The study highlights that oncologists on the frontline do prefer value-based care to optimize health-resource utilization. A concerted effort to perform an objective value assessment for each breakthrough therapy with measurement of willingness-to-pay threshold and budget impact calculation will be helpful to further assist oncologists in choosing the right drugs for patients without further burdening the limited health budget and resources.³⁰

Our findings must be considered in the light of methodologic limitations. First, the snowball methodology made it difficult to ascertain response rates in many countries, but the overall response was low including India. The methodology did not allow to have fixed proportion on the basis of the practice setting, country, or sex of oncologists. Accordingly, the survey respondents are not necessarily representative of all Indian oncologists. Our affordability evaluation was based on a pragmatic modification of a prior survey tool rather than a validated instrument.¹⁸ Because our conclusions on access to

medicines within a country are based on oncologists' perception rather than actual utilization data, there is a potential that these estimates may be inaccurate.

The findings from this study should serve as a collective call to action to address barriers to delivering high-quality and affordable cancer care across India. Cancer care in India is associated with significant financial toxicity, which translates into poor health-related quality of life, worsening financial status in households, deprioritization of their other needs, and treatment abandonment.^{28,31} Reduction in OOP expenditure for accessing essential health care, including anticancer drugs, should be one of the top priorities for policymakers (Table 5). Inclusion of the drugs in WHO-EML, NLEM, and the clinical guidelines has important implications but access needs further action to address the barriers because of quality, differential pricing, and stockouts. Novel strategies such as pooled procurement, negotiation at the national level, group contracting, stringent methods to identify quality generics and biosimilars, strengthening the regulatory processes to ensure maintenance of drug quality and supply beyond the marketing approval, and fair pricing will cumulatively serve to mitigate the problems identified in our study.³² Research efforts will identify new cancer therapeutics to improve the outcome of future patients. However, we must devote an equal amount of energy and attention to ensuring that all current patients have access to the treatments that we already know work. Ensuring access and affordability of cancer care in India and other LMICs should be one of the top priorities for governments and policymakers.

AFFILIATIONS

¹Department of Medical Oncology, Tata Memorial Centre, Homi Bhabha National Institute, Mumbai, India

²Division of Cancer Care and Epidemiology, Queen's University Cancer Research Institute, Kingston, Canada

³Department of Oncology, Queen's University, Kingston, Canada

⁴Department of Public Health Sciences, Queen's University, Kingston, Canada

⁵Department of Surgical Oncology, Tata Memorial Centre, Homi Bhabha National Institute, Mumbai, India

⁶Department of Medical Oncology, Cancer Institute (W.I.A.), Chennai, India

⁷Department of Medical Oncology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India

⁸Malankara Orthodox Syrian Church Medical College, Kolenchery, India

⁹Cancer Diseases Hospital, Lusaka, Zambia

¹⁰Division of Early Drug Development for Innovative Therapies, European Institute of Oncology IRCCS, Milan, Italy

¹¹Department of Noncommunicable Diseases, World Health Organization, Geneva, Switzerland

¹²Department of Medical Oncology, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands

¹³Department of Health Products Policy and Standards, World Health Organization, Geneva, Switzerland

¹⁴Institute of Cancer Policy, King's College London, London, United Kingdom

CORRESPONDING AUTHOR

Manju Sengar, MD, Department of Medical Oncology, Tata Memorial Centre, Affiliated to Homi Bhabha National University, Parel, Mumbai, India 400012; Twitter: @ManjuSengar7; e-mail: manju.sengar@gmail.com.

AUTHOR CONTRIBUTIONS

Conception and design: Manju Sengar, Adam Fundytus, Dorothy Lombe, Matthew Jalink, Bishal Gyawali, Felipe Roitberg, Lorenzo Moja, Richard Sullivan, Christopher M. Booth

Administrative support: Christopher M. Booth

Provision of study materials or patients: Christopher M. Booth

Collection and assembly of data: Manju Sengar, Adam Fundytus, Wilma Hopman, C.S. Pramesh, Venkatraman Radhakrishnan, Matthew Jalink, Dario Trapani, Christopher M. Booth

Data analysis and interpretation: Manju Sengar, Adam Fundytus, Wilma Hopman, C.S. Pramesh, Venkatraman Radhakrishnan, Prasanth Ganesan, Aju Mathew, Matthew Jalink, Bishal Gyawali, Dario Trapani, Felipe Roitberg, Elisabeth G.E. De Vries, Lorenzo Moja, André Ilbawi, Richard Sullivan, Christopher M. Booth

Manuscript writing: All authors

Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

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C.S. Pramesh

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Dorothy Lombe

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Bishal Gyawali

This author is a member of the *JCO Global Oncology* Editorial Board. Journal policy recused the author from having any role in the peer review of this manuscript.

Consulting or Advisory Role: Vivio Health

Felipe Roitberg

Honoraria: Boehringer Ingelheim, AstraZeneca, Oncologia Brasil

Consulting or Advisory Role: MSD Oncology

Research Funding: Roche (Inst), Boehringer Ingelheim (Inst), MSD (Inst), Bayer (Inst), AstraZeneca (Inst), Takeda (Inst)

Elisabeth G.E. De Vries

Consulting or Advisory Role: Daiichi Sankyo (Inst), NSABP Foundation (Inst), Crescendo Biologics (Inst)

Research Funding: Amgen (Inst), Synthon (Inst), CytomX Therapeutics (Inst), Regeneron (Inst), G1 Therapeutics (Inst), Bayer (Inst), Roche (Inst), Genentech (Inst), Servier (Inst), Crescendo Biologics (Inst)

Uncompensated Relationships: ESMO (Inst), World Health Organization (Inst), RECISt (Inst)

Richard Sullivan

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APPENDIX

TABLE A1. List of Drugs

Drug Names			
1. Abemaciclib	45. Dactinomycin	89. Lenvatinib	133. Regorafenib
2. Abiraterone	46. Daratumumab	90. Letrozole	134. Ribociclib
3. Acalabrutinib	47. Dasatinib	91. Leucovorin	135. Rituximab
4. Afatinib	48. Daunorubicin	92. Leuprolide	136. Romidepsin
5. Aldesleukin	49. Decitabine	93. Liposomal irinotecan	137. Ruxolitinib
6. Alectinib	50. Degarelix	94. Lomustine	138. Siltuximab
7. Alemtuzumab	51. Denosumab	95. Lorlatinib	139. Sorafenib
8. Amsacrine	52. Dexamethasone	96. Medroxyprogesterone	140. Strontium-89
9. Anagrelide	53. Dinutuximab	97. Megestrol acetate	141. Sunitinib
10. Anastrozole	54. Docetaxel	98. Melphalan	142. Tamoxifen
11. Apalutamide	55. Doxorubicin	99. Mercaptopurine	143. Talazoparib
12. Arsenic trioxide	56. Durvalumab	100. Methotrexate	144. Temozolomide
13. Atezolizumab	57. Elotuzumab	101. Midostaurin	145. Temsirolimus
14. Avelumab	58. Enzalutamide	102. Mitomycin	146. Thalidomide
15. Axitinib	59. Epirubicin	103. Mitotane	147. Thioguanine
16. Azacitidine	60. Eribulin	104. Mitoxantrone	148. Topotecan
17. Bendamustine	61. Erlotinib	105. Nab-paclitaxel	149. Trabectedin
18. Bevacizumab	62. Erwinia asparaginase	106. Nelarabine	150. Trametinib
19. Bicalutamide	63. Etoposide	107. Nilotinib	151. Trastuzumab
20. Bleomycin	64. Everolimus	108. Nilutamide	152. Tretinoin (ATRA)
21. Blinatumomab	65. Exemestane	109. Nivolumab	153. Trifluridine/tipiracil
22. Bortezomib	66. Fludarabine	110. Obinutuzumab	154. Triptorelin
23. Bosutinib	67. FU	111. Octreotide	155. Vandetanib
24. Brentuximab vedotin	68. Flutamide	112. Olaparib	156. Veliparib
25. Brigatinib	69. Fulvestrant	113. Osimertinib	157. Vemurafenib
26. Buserelin	70. Gefitinib	114. Oxaliplatin	158. Venetoclax
27. Busulfan	71. Gemcitabine	115. Paclitaxel	159. Vinblastine
28. Cabazitaxel	72. Goserelin	116. Palbociclib	160. Vincristine
29. Cabozantinib	73. Hydroxyurea	117. Pamidronate	161. Vinorelbine
30. Capecitabine	74. Ibrutinib	118. Panitumumab	162. Vismodegib
31. Carboplatin	75. Idarubicin	119. Pazopanib	163. Vorinostat
32. Carfilzomib	76. Idelalisib	120. Pegaspargase	164. Zoledronic acid
33. Carmustine	77. Ifosfamide	121. Pegylated liposomal doxorubicin	
34. Ceritinib	78. Imatinib	122. Pembrolizumab	
35. Cetuximab	79. Inotuzumab ozogamicin	123. Pemetrexed	
36. Chlorambucil	80. Interferon alfa-2b	124. Pertuzumab	
37. Cisplatin	81. Ipilimumab	125. Pomalidomide	
38. Cladribine	82. Irinotecan	126. Ponatinib	
39. Cobimetinib	83. Ixazomib	127. Pralatrexate	
40. Crizotinib	84. Trastuzumab emtansine (TDM-1)	128. Prednisone	
41. Cyclophosphamide	85. L-asparaginase	129. Procarbazine	
42. Cytarabine	86. Lanreotide	130. Radium-223	
43. Dabrafenib	87. Lapatinib	131. Raltitrexed	
44. Dacarbazine	88. Lenalidomide	132. Ramucirumab	

Abbreviation: FU, fluorouracil.

TABLE A2. Access to the 20 Most Frequently Selected High-Priority Medicines Identified by 67 Oncologists From LMICs Other Than India

Drug Name	No. ^a	Universally Available ^b	Significant OOP Expenses ^c	Risk of Catastrophic Expenditure ^d	Not Available
Doxorubicin	46	13 (28)	11 (24)	17 (37)	5 (11)
Cisplatin	39	11 (28)	11 (28)	14 (36)	3 (8)
Cyclophosphamide	38	12 (32)	10 (26)	12 (32)	4 (11)
Carboplatin	35	8 (23)	8 (23)	19 (54)	0 (0)
Paclitaxel	33	5 (15)	8 (24)	17 (52)	3 (9)
Capecitabine	32	6 (19)	9 (28)	16 (50)	1 (3)
Tamoxifen	30	9 (30)	10 (33)	8 (27)	3 (10)
FU	29	11 (38)	3 (10)	11 (38)	4 (14)
Oxaliplatin	23	6 (26)	4 (17)	12 (52)	1 (4)
Docetaxel	24	6 (25)	3 (13)	13 (54)	2 (8)
Gemcitabine	20	5 (25)	4 (20)	11 (55)	0 (0)
Dexamethasone	20	7 (35)	8 (40)	4 (20)	1 (5)
Vincristine	18	7 (39)	2 (11)	5 (28)	4 (22)
Etoposide	16	3 (19)	4 (25)	7 (44)	2 (13)
Trastuzumab	14	3 (21)	0 (0)	10 (71)	1 (7)
Methotrexate	12	5 (42)	1 (8)	4 (33)	2 (17)
Imatinib	11	5 (46)	4 (36)	2 (18)	0 (0)
Bleomycin	9	4 (44)	0 (0)	3 (33)	2 (22)
Rituximab	9	0 (0)	1 (11)	7 (78)	1 (11)
Leucovorin	8	3 (38)	1 (13)	3 (38)	1 (13)

NOTE. Percentages may exceed 100 because of rounding.

Abbreviations: FU, fluorouracil; LMICs, low- and middle-income countries; OOP, out-of-pocket.

^aResponses do not equal the number who selected the drug since many respondents made their drug selections and exited the survey; the number responding is provided in column 2.

^bAvailable for all patients with no significant out-of-pocket expenses for more than 90% of patients (ie, universal health care coverage).

^cAvailable for all patients with significant OOP expenses for some patients, on the basis of the health insurance schemes (mixed model, not universal health care coverage).

^dNot universal health care coverage, substantial risk of catastrophic health expenditure. Catastrophic expenditure defined as expenditure that absorbs more than 40% of total consumption, net of an allowance for food expenditures.