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Development of One Window Services Model in Accessing Immunotherapies by Cancer Patients in a Hospital in Rawalpindi, Pakistan: A Mixed Methods Study

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Abstract

Background: The primary cause of mortality, cancer, is predicted to rise 1.7 times in 2040 compared to 2018. Immunotherapies have transformed cancer treatment for advanced malignancies. Due to inadequate information, there are well-documented hurdles to getting cancer immunotherapies, increasing the disease's burden. This study aims to develop a One-Window Services Model (OWSM) for gaining access to cancer immunotherapies.

Methods: This was a sequential explanatory mixed-method study. The quantitative part used interviewer-administered questionnaires including data on knowledge and attitude in conveniently selected 20 cancer patients, and data were analyzed through SPSS. The qualitative part used an open-ended questionnaire for In-depth interviews (IDIs) along with the results of the quantitative part in purposively selected seven tumor panel physicians (TPP) and analyzed by grounded theory. The study was conducted in a specialized tertiary care bone marrow hospital in Rawalpindi, Pakistan.

Results: The findings of the quantitative part presented that 80% of cancer patients had poor knowledge about processes, and 90% had a positive attitude towards their cancer immunotherapies. The findings of the qualitative part presented additional evidence that explained some unclear issues and expanded the results of quantitative data, which were presented as a broader theme "tools for OWSM" through IDI and followed by development of ten steps of OWSM.

Conclusion: The sequential explanatory mixed method was considered appropriate for developing the ten steps of OWSM since it involved knowledge and attitude as integral parts of behavior change of patients based on Andersen's theoretical framework of health service use and the advice of experts. Moreover, the model will be tested in an experimental effectiveness trial planned in next phase .

Keywords: One window services model, cancer immunotherapies accessibility, Andersen's service use behavioral model, mixed-methods, Pakistan

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Introduction

Cancer is a leading cause of death, with nearly 10 million or one in six deaths worldwide in 2020(1). In 2020, 18 million new cases were recorded globally. By 2040, that number will rise to almost 30 million, with nearly 17 million fatalities, 1.7 times greater than in 2018(2) The Southeast Asian region had 20 million new cases and 13 million deaths out of 2 billion population; amongst that region, only Pakistan had 0.174 million new cases and 0.12 million deaths out of 22 million people in 2020(3,4). Around 33 % of deaths from cancer are due to smoking, obesity, alcohol use, low fiber intake, and physical immobility(5). The most frequently available cancer treatments include surgery, radiation or chemotherapy, hormone therapy, targeted therapy, and stem cell transplant, usually administered according to international and national protocol-guided combinations(6).

Immunotherapies have been added to these treatments since 2018. They are biological therapies, using substances made from living organisms to kill cancer cells. Immunotherapies have improved survival in patients with cancers previously unresponsive to chemotherapy, revolutionizing care for many patients with advanced cancers[6]. Between 2010 and 2021, the US Food and Drug Administration (FDA) approved immunotherapy for 19 cancer types(7).

Accumulating evidence had documented barriers to accessing immunotherapies. Socioeconomic factors such as low income, employment status, knowledge levels, and lack of health insurance are other significant barriers to accessing treatments. Clinical factors such as comorbid conditions and physical disability of cancer patients may be individual-level barriers to accessing immunotherapy. Organizational factors such as referral systems, geographical access, competent services model, and lack of integration of health system with other systems also increased the probability of missing or delaying effective

treatments(8,9). Access to needed treatment is central to the health system and a prominent health policy subject (10).

One window services model (OWSM) is defined as a service operation in which a single server may satisfy all of a patient's needs without waiting in a second queue(11). Globally, it has been used progressively in several services such as social, health, employment, and services for entrepreneurs and small businesses and international trade through a single-entry point. Many organizations also use it as a single point of validation and delivery. Its principal focus is improving service delivery efficiency through simplifying and harmonizing processes, procedures, and information flows.

Pakistan single window is a newly launched trade system that provides a facility to parties involved in trade and transport to lodge standardized information and documents with a single-entry point to fulfill all import, export, and transit-related regulatory requirements. This initiative is mainly linked with customs, commercial banks, regulatory agencies, women-led businesses, and logistic services(12).

After searching the database of google scholar, research gate, PubMed, and from Chulalongkorn university library in the English language with the keywords Pakistan, One window services model, development of services model, Accessibility models, Andersen's health service use model, from "2013 to 2023" there were not identified studies jointly looking development of OWSM in accessing cancer immunotherapies globally. However, two review papers, one on strategies for immunotherapies and the second on access to cancer facilities(13,14). The other two were on the availability of anticancer medicines in the public and private sectors(15).

This study aims to develop OWSM for cancer patients accessing cancer immunotherapies based on mixed methods.

Methodology

Study Design

This was designed as a sequential explanatory mixed-method study. The quantitative part had a survey with an interviewer-administered questionnaire. The qualitative part had a Grounded Theory design through IDI.

Study Setting and Population

In a hospital-based study in Rawalpindi, the population was cancer patients for a quantitative survey and TPP for the qualitative part.

Sample Size and sampling technique

Twenty cancer patients on the day of the administration of the questionnaire were selected conveniently because all of them were available on the day of the interview, the researcher had connections with the hospital for a quantitative survey, and all 7 TPP were selected purposively for the qualitative part.

Inclusion & exclusion criteria of the quantitative part

The inclusion criteria were Pakistani cancer patients advised to receive immunotherapies by TPP, aged 18 years or over, treated in the study hospital, with good physical conditions to complete all related tasks, and screened by the hospital finance department. The exclusion criteria were cancer patients with a previous history of drug reactions, who refused to sign the consent forms, and in stage 4 or on palliative care.

Instrument and process for Data collection

For the quantitative survey, data were collected one day, constructed from the previous study(16). The questionnaire consisted of five sections. The first section was predisposing factors, including six questions (Q1–6) on the socio-demographic characteristics (1. age, 2. gender, 3. marital status, 4. education, 5. ethnicity, 6. religion). The second section was enabling factors, which included ten questions (Q7–16) on personal and organizational factors (1. monthly family income, 2. occupation, 3. employment status, 4. insurance policy, 5. kind of an insurance policy, 6. out-of-pocket money to buy, 7. information by the hospital pharmacy, 8. estimated cost by the hospital pharmacy, estimated time by the hospital pharmacy, 10 pharmacy staff accountability). The third section was need factors, included six questions (Q17–22) on personal and evaluated needs (1. duration of disease, 2. family medical history, 3. presenting symptoms, 4. type of cancer,5. clinical staging,6. previously received treatments). The fourth section on knowledge included ten questions (Q23–32) that were measured with options (no=0 and yes=1). (1 awareness of treatment protocol, 2. willingness to learn the process, 3. knowledge of the availability of prescribed immunotherapy, 4. information on how to get your prescribed cancer immunotherapy, 5. Knowledge of the timeline to get prescribed cancer immunotherapy, 6. Knowledge about the required documents to get permission for import from the drug regulatory authority of Pakistan, 7. Knowledge of financial transaction process to import immunotherapy, 8. Knowledge about logistic channels for accessing immunotherapy, 9. Knowledge about required documents for customs clearance, 10. Knowledge of documents for delivering and receiving your prescribed immunotherapy by the hospital pharmacy). The knowledge was described by three categories "excellent, Average, and poor knowledge," according to Bloom's cut-off points, 80.0%–100.0%, 60.0%–79.0%, and ≤59.0%, respectively.(17)and the fifth on Attitudes included six questions measured using a 5-point Likert scale ranging from (1 Strongly disagree, 2 disagree, 3 neutral, 4 agree, and 5 Strongly agree). (1. prefer to be treated by a physician with an aggressive approach toward cancer treatment protocols,2. I prefer to be treated by a physician with more focus on treatment, dosage, and treatment time than my emotional reactions,3. feel pessimistic about the outcome of my prescribed cancer immunotherapy, 4. feel optimistic about control of cancer with the latest cancer immunotherapies in the foreseeable future,5. prefer to refuse chemotherapy or radiotherapy rather than suffering from its serious side effects, 6. feel my quality of life would be much better with my prescribed immunotherapy compared to chemotherapy or radiation). The attitudes were divided into two categories 1. Positive attitude, 2. Negative attitude by using mean value. The value above the mean value is considered a "positive attitude," and the value below the mean value is considered a "negative value."

Therefore, this instrument contained 39 items and was tested for content validity by five professionals. The content validity index (CVI) ranged from 0.81 to 0.97. A reliability

level of the knowledge dimension at 0.88 was obtained by the Kuder Richardson (KR-20) analysis. Reliability levels were reported at 0.81 for the attitude dimension from Cronbach's alpha coefficient analysis.

For the qualitative part, IDI facilitated with quantitative results and an open-ended semi-structured questionnaire containing four domains: (1) regulatory, (2) procurement, (3) treatment, and (4) patients and 12 questions were adapted from similar research (18)was conducted with TPP individually, for 30–60 audio–recorded min interview. Confidentiality was assured to facilitate candid discussions, and interviews were held in a private space. The researcher conducted all the interviews face-to-face, and recorded responses R were transcribed into a broad theme used for developing OWSM.

The Research Ethics Review Committee for Research Involving Human Research Participants,

Group I, Chulalongkorn University, has approved: Study Title No. 650125, Date of Approval 09 Dec 2022, COA No. 235/65 for phase 1 development of OWSM and experimenting with the model as phase 2 of the research.

Data analysis

For the quantitative part, the data was analyzed by SPSS (Version 26). Descriptive statistics presented all variables from five questionnaire sections through frequency, percentage, and means for attitude.

The qualitative part was analyzed in MAXQDA's In-vivo software. The researcher coded the data from IDI supported by respondents' relevant quotes by applying the grounded theory. Triangulation was done from four domains supported by their relevant quote for the development of OWSM.

Besides, the researcher frequently cross-checked the URDU audio versus the English transcription through trint software during the coding process to ensure that the information's essence was recovered. The researcher reviewed most of the written translations against the audio for validation. An external qualitative research expert reviewed all themes and sub-themes and agreed on adjustments or modifications with the researcher.

Results

The study results were:

1. The quantitative part presented knowledge and attitude of cancer patients
2. The qualitative part presented a broad theme, "tools of OWSM," through IDI from TTP 3. Development of ten steps OWSM.

Descriptive analysis of quantitative results

The analysis of the summation of all items of the predisposing factors revealed that 40% of respondents were aged (18-33), 65% were male, 60% were married, 35% education at college/university level, 40% were Punjabi ethnicity, and 80% were Muslims.

The analysis of the summation of all items of the enabling factors revealed that 70% of respondents were employed, and 60% had no insurance (results not tabled). In Table 1, 55% of respondents did not get information from a pharmacy,65% about where they got immunotherapy, 60% about the estimated timeline, 75% for the estimated cost, and 65% from accountable pharmacy staff. (More details in Table 1)

Table.1 Enabling factors characteristics (n= 20) of cancer patients in accessing immunotherapies

Variable	Categories	Frequency (n)	Percentage (%)
Insurance Policy	No	12	60.0
	Yes	8	40.0
Insurance kind/type	None	12	60.0
	Government	2	10.0
	Semi-Government	1	5.0
	Private	4	20.0
	Armed Forces	1	5.0
Enough out-of-pocket money	No	15	75.0
	Yes	5	25.0
Information from the hospital pharmacy	No	11	55.0
	Yes	9	45.0
Immunotherapy Estimated cost	No	12	60.0
	Yes	8	40.0
Estimated immunotherapy Arrival Time	No	14	70.0
	Yes	6	30.0
Accountable Staff for immunotherapy distribution	No	13	65.0
	Yes	7	35.0

Need factors:

The analysis of the summation of all items of the need factors revealed that 75% of the respondents have a family medical history of cancer and were diagnosed with stage 3 and 40% of respondents had a disease duration of 12-24 months and had previously received chemotherapy. (see table 2)

Table.2 Need factors characteristics (n= 20) of cancer patients in accessing immunotherapies

Variables	Categories	Frequency (n)	Percentage (%)
Duration disease	≤ 12 months	7	35.0
	13-24 months	8	40.0
	25-36 months	5	25.0
Family medical history of cancer	No	15	75.0
	Yes	5	20.0
Most presenting symptom	Changes in skin	7	35.0
	Lump or area of thickening felt under the skin	13	65.0
Type of cancer	Leukemia	8	40.0
	Lymphoma	12	60.0
Clinical stage of cancer	Stage II	5	25.0
	Stage III	15	75.0
Treatments received previously	Surgery	6	30.0
	Radiotherapy	6	30.0
	Chemotherapy	8	40.0

Knowledge

The analysis of the summation of all knowledge items revealed that 95% of the respondents knew about their treatment protocol and needed to learn how to get immunotherapy. Also, 95% of respondents still need to receive information about availability and timeline from the tumor panel, and 85% did not receive any information about documents for financial transactions, logistics, customs, and from the pharmacy. (More details in Table 3)

The analysis of the summation of all items of the knowledge into three categories revealed that 80% of the respondents have poor knowledge, 5% have average and 15% have excellent knowledge (Bloom cut of point) (see details in Table 4)

Attitude

The analysis of the attitudes is presented into two categories, negative and positive, based on the mean values of all respondents, which was 15.90. All respondents who scored above the mean value were considered to have a positive attitude, and those who scored below the mean were rated as having a negative attitude. Results revealed that (90%) of the respondents have a positive attitude towards and 10 % have a negative attitude towards their preferences towards immunotherapies. (see details in Table 5)

Table.3 Knowledge characteristics (n= 20) of cancer patients in accessing immunotherapies

Patients know of	Categories	Frequency (n)	Percentage (%)
current t/m protocol	No	1	5.0
	Yes	19	95.0
Need to Learn more about how to get immunotherapy	No	1	5.0
	Yes	19	95.0
Countries in which prescribed immunotherapy is available	No	19	95.0
	Yes	1	5.0
information by Tumor panel physician?	No	19	95.0
	Yes	1	5.0
Timeline by tumor panel p?	No	19	95.0
	Yes	1	5.0
Required documents to get import permission	No	17	85.0
	Yes	3	15.0
Financial transaction process	No	17	85.0
	Yes	3	15.0
Import Logistics channels	No	17	85.0
	Yes	3	15.0
Documents to submit to the customs	No	18	90.0
	Yes	2	10.0
Documents for delivery and receiving prescribed immunotherapy	No	14	70.0
	Yes	6	30.0

Table.4 Knowledge categories (n= 20) of cancer patients in accessing immunotherapies

Variable	Categories	Frequency (n)	Percentage (%)
Knowledge	Poor knowledge	16	80.0
	Average knowledge	1	5.0
	Excellent knowledge	3	15.0

For The qualitative part, results are presented in (Table 6)

The qualitative part of the study used previous results from the quantitative survey and an open-ended questionnaire for seven TTP for IDI. All the responses gave a broader theme through the coding process from translated audio to English text and then transcribed text into subcategories, categories, codes, and then theme as follows.

Table 5: Attitude characteristics (n=20) of cancer patients in accessing immunotherapies

Variable	Categories	Frequency (n)	Percentage (%)
Aggressive approach towards cancer t/m	Disagree	4	20.0
	Agree	11	55.0
	Strongly agree	5	25.0
Focus on t/m, dosage, and time	Strongly disagree	1	5.0
	Disagree	7	35.0
	Agree	11	55.0
	Strongly agree	1	5.0
Pessimistic about the outcome	Strongly disagree	2	10.0
	Agree	16	80.0
	Neutral	2	10.0
Optimistic about control of cancer	Disagree	2	10.0
	Agree	13	65.0
	Strongly agree	5	25.0
Refuse chemotherapy or radiotherapy	Strongly disagree	1	5.0
	Agree	16	80.0
	Neutral	2	10.0
	Agree	1	5.0
QOL would be much better with my prescribed immunotherapy	Disagree	2	10.0
	Neutral	1	5.0
	Agree	13	65.0
	Strongly agree	4	20.0

Table 6: Categories of Attitude (n=20) of cancer patients in accessing immunotherapies

Variable	Categories	Frequency (n)	Percentage (%)
Attitude	Negative attitude	2	10.0
	Positive attitude	18	90.0

Table 7: Coding process from text to theme

Text	Subcategory	Categories	Code	Theme
You know main challenge is "We don't know the exact requirements for regulatory approval "it can be accelerated through awareness because we don't know approval pathway. (Specialist from tumor panel)	Requirements	Knowledge	Individual	
"The Problem is that our institution has procurement issues due to not having adequate information in accessibility of such medications" (Specialist from tumor panel)	Information	Knowledge	Organizational	**Tools to develop OWSM**
"We would like to know about national/international guidelines for required treatment protocols" as there is not any integrated system."	Guidelines	Attitude	Organizational	
"In fact, we think that patient participation in awareness activities in communities should be up to every individual patient".	Awareness	Attitude	Community	

Development of Steps of OWSM

OWSM comprised ten steps based on responses from an interviewer-administered questionnaire from 20 cancer patients and endorsed by 7 TTP perspectives from an open-ended questionnaire.

Step 1: Awareness of cancer patients was achieved by developing an instruction manual containing all links and information with examples to navigate the process. Contents of the manual came from responses to the knowledge part of questionnaires and open-ended questions interviewed with TPP through IDI. Patients received a QR code to enter the manual awareness portal.

Step 2 To address shortcomings from the knowledge part of the questionnaire (see Table 3) and the TPP responses (see Table 5), registration enrollment was developed from the user manual of DRAP. The patient can get approval on his name for up to 100 doses. Application for import of medicines made by the patient, limited to the maximum supply of one hundred doses (100 doses).

Step 3 To address shortcomings from the knowledge part of the questionnaire (see Table 3) and from the TPP responses (see Table 5) link was added for online application for submitting a valid prescription from a registered medical practitioner with a registration number, National identity card of patient and list medicines along with name, manufacturer, and quantities from the user manual of DRAP. No objection certificate is issued within 24 hours.

Step 4: To address shortcomings from the knowledge part of the questionnaire (see Table 3) and the TPP responses (see Table 5), a comparison analysis was developed by mapping guidelines provided by the respective manufacturer through their authorized distributors for the respective region.

Steps 5 To address shortcomings from the knowledge part of the questionnaire (see Table 3) guidelines for the contract between the patient and authorized distributor.

Step 6 To address shortcomings from the knowledge part of the questionnaire (see Table 3 guidelines adopted from the foreign exchange manual of Pakistan for financial transactions.

Step 7 To address shortcomings from the knowledge part of the questionnaire (see Table 3), guidelines for the logistics were developed by guidelines from the user manual of DRAP.

Steps 8 To address shortcomings from the knowledge part of the questionnaire (see Table 3), guidelines were developed for customs clearance by guidelines from the user manual of DRAP. There was a pre-clearance mechanism in practice known as ICG (Immediate Clearance Group), which operated 24 hours and 7 days a week to clear temperature-sensitive goods, including immunotherapies, immediately.

Step 9 To address shortcomings from the knowledge part of the questionnaire (see table 3) and from the panel physician responses guidelines developed for supervision till delivery from the EU GDP.

Step 10 To address shortcomings from the knowledge part of the questionnaire (see Table 3), guidelines for the feedback form adopted from the manufacturer are directly

duly signed by the hospital pharmacy staff and patient.

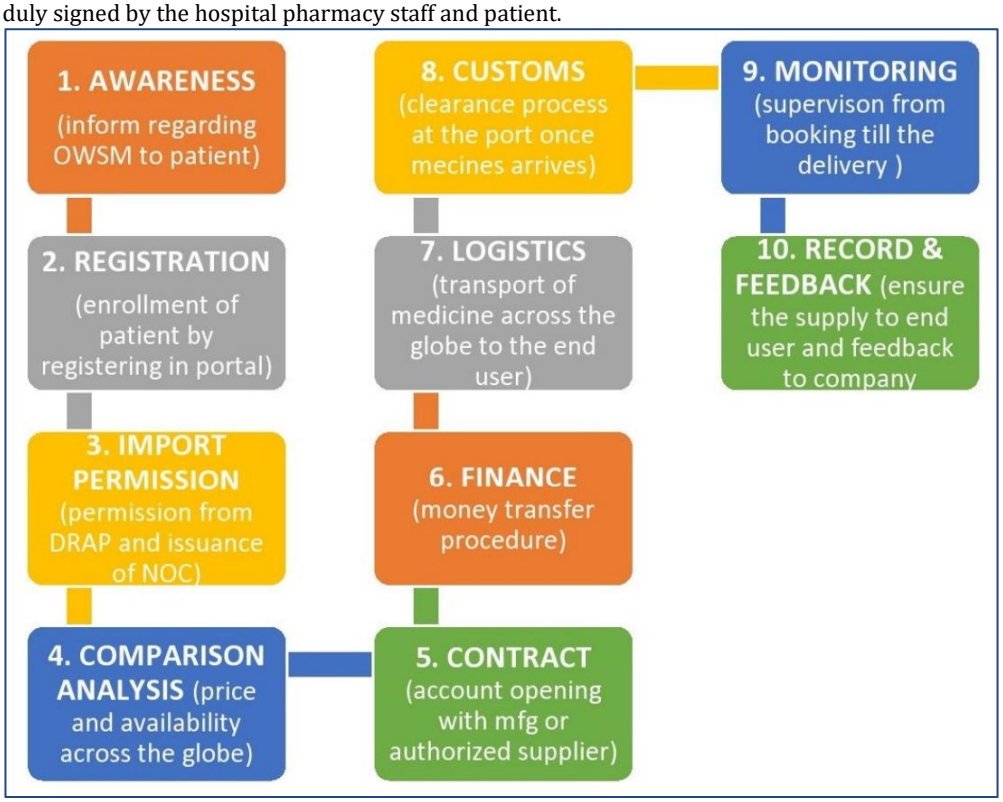

Figure 1: Development of Steps of OWSM

Discussion

This study used a sequential explanatory mixed method due to its straightforwardness and opportunities for an in-depth explanation of the quantitative results. Previous studies on the development of effective instruments for service delivery management also used mixed methods and grounded theory(19).

The study's findings showed that most reported cancer patients were young males below 33 years of age. The meta-analysis from previous studies showed, however, that patients with age 65 years or more had significantly improved OS as compared to young patients, and generally, immunotherapy may result in less effective in women than in males. Furthermore, the increased antigenicity in male cancers explains why immunotherapy is more effective in males(20,21).

The study also found that 70 percent of cancer patients have a family history of cancer and have been diagnosed with stage 111; all have been previously treated with either surgery, radiotherapy, or chemotherapy. A relevant pilot study linked family medical history as possible predictive surrogates of clinical benefit for immunotherapies treatments(22).

The enabling factors findings showed that all cancer patients did not receive complete information from pharmacy staff about the accessibility, cost, and timeline of their prescribed immunotherapy. Information is key to knowledge, and lacking information is an important barrier to accessing immunotherapy. Previous studies linked the importance of pharmacy information in the use of immunotherapy(23)

Knowledge is the key element to change the behavior of individuals, particularly in health-seeking behavior. The study's findings showed that 80% of cancer patients have poor knowledge about getting their immunotherapies due to missing information from the TPP. Previous studies have found that knowledge of cancer immunotherapy was limited. To increase their knowledge of modern immunotherapy, cancer patients need information on their country's best practice guidelines to enhance their immunotherapy experience, insurance coverage adjustment policies, logistic concerns, and resource constraints that patients and clinicians encounter(24).

Similarly, attitudes play a critical role in behavior change. The findings of the attitudes part showed that 90% of cancer patients have positive attitudes towards the use of cancer immunotherapies, and they feel very optimistic regarding the results of immunotherapies. A previous study on knowledge and attitudes showed that patient knowledge of cancer immunotherapies was limited, although their attitudes were generally favorable, and their expectations were high(25). Immunotherapies are the most widely studied worldwide and are now approved for multiple cancers. Patient education should be prioritized along with the development of novel cancer immunotherapy treatments(26).

The qualitative data findings presented additional evidence that explained some unclear issues and expanded the results of quantitative data. Study results of both 20 cancer patients from the quantitative data and an open-ended questionnaire to get in-depth information from TPP through IDI. Through the TPP perspectives, the study

generated a broader theme, tools to develop OWSM.

Steps were designed to address the broader theme of each shortcoming that came out through IDI, as explained in Fig 1. One advantage of OWSM is integrating all the information in an instruction manual to share with cancer patients to access their immunotherapies efficiently. Several previous studies have also used the mixed method to develop an instruction model to improve service delivery in health care systems, including mental health care delivery and caesarian deliveries care(27).

Conclusion

The sequential explanatory mixed method was considered appropriate for developing the ten steps of OWSM since it involved knowledge and attitude as integral parts of behavior change of patients based on Andersen's theoretical framework of health service use and the advice of experts. The model will be tested in an experimental effectiveness trial planned in phase 2.

Limitations

- The study was urban and conducted in one hospital only, missing out on the viewpoint of other hospitals. Due to limited time and resources, interviews in Urdu were translated into English, not transcribed, and written directly into English.
- The self-reported Knowledge questions had "yes or no" answers and had less validity in assessing the respondent's knowledge compared to knowledge questions with multiple-choice answers.

Recommendations

Further studies must be conducted:

- To assess the acceptability, feasibility, and effectiveness of OWSM for experimental trial as planned for phase two of this study.
- To partner with existing research agencies or universities' faculties of public health as in developed countries.
- To identify other areas of study with a particular focus on health economics.
- Using a questionnaire that measures respondent knowledge directly, not self-reported knowledge.

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