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Development of a Saudi Palliative Care Essential Medication List (EML)

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Abbreviations: EML: Essential Saudi Palliative Medication List; WHO: World Health Organization; PC: Palliative Care; SPSS: Statistical Package for the Social Sciences; IR: Immediate Release; SR: Sustained Release; SHC: Saudi Health Council; KSA: Kingdom of Saudi Arabia; MOH: Ministry of Health

ABSTRACT

Background: In response to the request of the Saudi Health Council, an expert palliative multi-disciplinary central committee was created to develop a model of the essential Saudi palliative medication list (EML), to be updated every 2 years, based on the World Health Organization (WHO) criteria for EML.

Objectives: Our aim was to explore the degree of consensus among physicians involved in palliative care (PC) regarding appropriate pharmacological treatment for common symptoms of palliative patients with cancer and to thus develop a national medication list of essential medicines for PC based on expert opinion. This list will serve as a key for future decision making in clinical practice.

Methods: We conducted a descriptive cross-sectional study of all consultants from July 2020 to August 2020. A structured questionnaire was used to collect the data, which were analyzed using Statistical Package for the Social Sciences (SPSS) version 25.

Results: The top palliative consultant experts in the Kingdom of Saudi Arabia participated in the study, with a high level of consensus among the experts. More than 60 medications were included in the review. The survey influenced the PC medication list following consensus. The preference for a medication was grouped into three categories—mandatory, necessary, and optional—based on administration frequency and the specified categories. The "mandatory" medications such as baclofen tablets, loperamide, ibuprofen tablets, midazolam injections, Tylenol III and fentanyl injections, morphine injections, morphine (IR) syrup, and morphine (SR) tablets were considered. The "necessary" medications such as modafinil tablets, morphine (SR) 60 mg, megestrol, and prednisone were considered. The "optional" medications included the following: fentanyl 500 mcg injections, hydrocortisone cream, and atropine eye drops.

Conclusions: The drugs prescribed and reported in this survey can be incorporated with the WHO EML, which in turn can lead to a constructive change in local drug policies and provide a basis for the minimum standard of care for PC institutions.

Introduction

Palliative care (PC) is an approach that enhances the quality of life of patients (adults and children) and their families who are dealing with complications related to life-threatening illnesses [1]. Such care prevents and relieves discomfort by detecting, assessing, and treating pain and other symptoms as early as possible, including medical, psychosocial, and moral issues. In June 2018, the Saudi Palliative Care National Clinical Guidelines for Oncology were established. These guidelines were developed to include proof- and consensus-based recommendations for best practice advice for a variety of common clinical problems in PC. They also serve as a comprehensive roadmap for healthcare practitioners to standardize practice in order to ensure the highest level of care for PC patients and their families, which supports both generalist and specialty PC providers [2]. Since the World Health Organization (WHO) first introduced the definition of essential drugs, it has become an important component of national health-care policies and activities. The importance of vital drugs combined with healthcare programs is being strengthened as health institutions work for universal health coverage. This incorporation enables prescribing doctors to provide treatment for patients without jeopardizing the patient's care due to the consequences of their therapy and financial condition, so patients should be able to access the clinical benefits they need without encountering insurance problems [2,3]. Currently, certain PC drugs are listed in the related portions of the WHO Expert Committee Model List based on their medicinal application, with analgesics being a particular example [4].

Based on expert views, PC organizations and agencies have identified or created lists of important medicines for PC [5-7]. The WHO has created a Model List of Essential Medicines (EML), which is revised every two years and is dependent on each medicine's reliability, efficacy, and cost-effectiveness [8,9]. In response to the Saudi Health Council (SHC) request, an expert palliative multi-disciplinary central committee was formulated to develop a model of Saudi essential palliative medication lists (EML) to be updated every 2 years, based on the WHO criteria of EML (the safety, efficacy and cost-effectiveness of each medicine listed) [9]. The definition and EML were suggested as expert recommendations to the Kingdom of Saudi Arabia (KSA) in order to establish national PC critical medicine policies and lists. The SHC has created recommendations with the aim of assisting all healthcare professionals interested in the treatment of palliative patients in the implementation of national Saudi critical medicine policies and lists for PC. Essential drugs are those that meet the majority of the population's healthcare needs [10,11]. They are chosen based on their importance to public health, proof of efficacy and safety, and comparative cost-effectiveness [9-11]. It is recommended that essential drugs be made available at all times within the framework of working health institutions, in sufficient quantities, suitable dosage types, with assured quality and adequate detail, and at a price that individuals and the community can afford [12]. The EML can be used as a starting point for future changes, such as the inclusion or elimination of old or new medications [13]. Policymakers in national health care systems will use the EML to pick available drugs on the market that will fulfill their country's healthcare needs while being cost-effective [13,14]. Our problem where in most palliative patients do not have access to the necessary drugs, despite evidence of drug efficacy, to alleviate their most common symptoms. Our aim was therefore to explore the degree of consensus among physicians working in specialist PC regarding appropriate pharmacological treatment for common symptoms for palliative patients with cancer, and to develop a national list of essential medicines for PC, based on expert opinion, that will serve as a key aid for decision making in future practice.

Methodology

Study Design/Setting

From July to August 2020, we performed a descriptive cross-sectional analysis of all consultants. For the current study, a standardized questionnaire was used, with the emphasis on the particular frequency of treatment used by the WHO EML. We did, however, gather data through a monkey survey.

Study Population

Our population included PC consultants who were selected based on their expertise. Demographics, career history as a PC physician, and a multidisciplinary team were among the information gathered.

Data Source

The central committee distributed the surveys to top PC experts in the KSA. Experts were defined as physicians currently working in specialist PC units, with at least 2 years of practice as a PC physician. The selection criteria were as follows: senior PC consultant, academic or research interest, and geographical distribution of different healthcare providers. All participants were recruited from different KSA regions in the PC units through each PC unit's representative. Representatives were asked to contact experts. The selected physicians from different PC units received an e-mail invitation to participate in the survey to develop the final list by listing their first and second choices of generic drugs. The response rate was 70%. In the second ad hoc group discussion, the most common symptoms in PC were identified, and their medications were included in the list of essential medicines for palliative care. The survey results changed the PC medication list draft according to the majority vote. While this list was not based on scientific evidence, but rather on expert opinion, the

expert committee finalized the lists to include the classification of "mandatory," "essential," and "optional" PC sections of the EML.

Variable Definitions

The questionnaire was divided into two sections. The first section included demographic data such as age, sex, job position, organization, and years of experience in PC. In the second section, experts had to classify the palliative medications into three categories: mandatory, necessary, and optional.

Statistical Analysis

The data were analyzed using Statistical Package for the Social Sciences (SPSS) version 25. Descriptive data were reported as frequencies and percentages to examine the distribution of study variables among the three categories.

Ethical Considerations

The Institutional Review Board of King Fahad Medical City in Riyadh, Saudi Arabia, reviewed and approved this study.

Results

Total of 12 Consultants participated in the study, 72.7% of whom were female and 18.2% of whom were male. Working experience ranged from less than five years to more than 11 years. Of the participants, 36.4% had 6 to 10 years of experience. The percentage of participants with less than 5 years and more than 11 years of experience was 27.3% in each group. Participants were from the Ministry of Defense Hospitals (9.1%), Ministry of Health Hospitals (72.7%), and Ministry of the Interior Hospitals (9.1%) (Table 1). Preferences for medication were grouped into three categories: mandatory, necessary, and optional. The frequency of administration of each medication was reviewed based on the specified categories. Ninety percent of the participants reported that baclofen 10mg tablets were "Mandatory," followed by loperamide 2mg capsules, ibuprofen 400mg tablets, and midazolam 15mg/3 mL injections. Tylenol III (acetaminophen 300mg & codeine 30mg) and fentanyl 100mcg injections were considered "Mandatory" by 80% of the participants, followed by morphine 10mg/mL injections, morphine (IR) 10mg/5mL syrup, morphine (SR) 10mg tablets, morphine (SR) 30mg tablets, tramadol 100mg injections, tramadol 100mg injections, lorazepam 1mg tablets, dexamethasone 8mg/2mL injections, dexamethasone 8mg tablets, haloperidol 5mg/mL injections, octreotide 100mcg/mL injections, hyoscine butyl bromide 20mg/mL injections, and more, as shown in Table 2.

Table 1: Palliative Care Medication Survey Result.

Variables	Mandatory		Necessary		Optional	
	(n)	(%)	(n)	(%)	(n)	(%)
Morphine 10mg/ml injection	7	70	3	30	0	0
Morphine (IR) 10mg tablet	6	60	4	40	0	0
Morphine (IR) 10mg/5ml syrup	7	70	3	30	0	0
Morphine (SR) 10mg tablet	7	70	3	30	0	0
Morphine (SR) 30mg tablet	7	70	3	30	0	0
Morphine (SR) 60mg tablet	3	30	5	50	2	20
Fentanyl 100 mcg injection	8	80	2	20	0	0
Fentanyl 500 mcg injection	2	20	3	30	5	50
Fentanyl 25 mcg patch	6	60	4	40	0	0
Fentanyl 50 mcg patch	5	50	3	30	2	20
Fentanyl 100 mcg sublingual tablet	4	40	3	30	3	30
Codeine phosphate 30mg tablet	6	60	1	10	3	30
Tylenol III (Acetaminophen 300mg &	8	80	1	10	1	10
Tramadol 100mg injection	7	70	0	0	3	30
Tramadol 50mg tablet	5	50	3	30	2	20
Tramadol 100mg tablet	4	40	3	30	3	30
Naloxone 0.4mg/ml injection	7	70	3	30	0	0
Acetaminophen 500mg tablet	8	80	2	20	0	0
Ibuprofen 400mg tablet	8	80	2	20	0	0
Midazolam 15mg/3ml injection	8	80	2	20	0	0
Lorazepam 1mg tablet	7	70	3	30	0	0
Atropine eye drops 1%	4	40	2	20	4	40
Benztropine 2mg/2ml injection	6	60	2	20	2	20
Dexamethasone 8mg/2ml injection	7	70	2	20	1	10

Dexamethasone 8mg tablet	7	70	2	20	1	10
Prednisone 10mg tablet	3	30	4	40	3	30
Hydrocortisone cream	4	40	1	10	5	50
Haloperidol 5mg/ml injection	7	70	3	30	0	0
Octreotide 100mcg/ml injection	7	70	3	30	0	0
Hyoscine butyl bromide 20mg/1ml injection	7	70	3	30	0	0
Glycopyrronium 200mcg/ml injection	7	70	3	30	0	0
Metoclopramide 10mg/2ml injection	7	70	3	30	0	0
Metoclopramide 10mg tablet	7	70	3	30	0	0
Diphenhydramine 25mg tablet	6	60	4	40	0	0
Diphenhydramine 25mg injection	7	70	3	30	0	0
Bisacodyl 5mg tablet	7	70	3	30	0	0
Bisacodyl 10mg suppositories	7	70	3	30	0	0
Docusate sodium 100mg capsules	6	60	3	30	1	10
Senna 8mg tablet	7	70	3	30	0	0
Lactulose solution	8	80	2	20	0	0
Glycerine suppositories	7	70	3	30	0	0
Fleet enema	7	70	2	20	1	10
Loperamide 2mg capsules	8	80	1	10	1	10
Nystatin 100,000 units/ml oral liquid	7	70	3	30	0	0
Pregabalin 50mg and 150mg capsules	7	70	3	30	0	0
Gabapentin 300mg and 800mg capsules	5	50	5	50	0	0
Levetiracetam 500mg tablet	6	60	3	30	1	10
Levetiracetam 100mg/ml syrup	6	60	3	30	1	10
Levetiracetam 100mg/ml injection	7	70	2	20	1	10
Modafinil 100mg tablet	2	20	6	60	2	20
Megestrol	2	20	5	50	3	30
Escitalopram 10mg tablet	6	60	4	40	0	0
Mertazapine 30mg tablet	6	60	4	40	0	0
Baclofen 10mg tablet	9	90	1	10	0	0
Furosemide 40mg tablet	6	60	3	30	1	10
Furosemide 10mg/ml	7	70	2	20	1	10
Bisphosphonate (Zoledronic acid, Pamidronate)	6	60	4	40	0	0
Vitamin D and Calcium	4	40	3	30	3	30

Table 2: National Palliative Care Medication List.

Mandatory	Necessary	Optional
Morphine 10mg/ml injection	Hydromorphone 2mg/ml injection	oxycodone 10mg/ml injection
Morphine (IR) 10mg tablet	Hydromorphone (IR)2mg tablet	Oxycodone 5mg immediate release tablet
Morphine (IR) 10mg/5ml syrup	Hydromorphone (SR) 4mg tablet	Oxycodone 10mg sustained release tablet
Morphine (SR) 10mg tablet	Methadone 5mg tablet	Buprenorphine 5mcg/hr patch
Morphine (SR) 30mg tablet	Fentanyl 12 mcg patch	Buprenorphine 10mcg/hr patch
Morphine (SR) 60mg tablet	fentanyl 200 mcg sublingual tablet	Methadone 2mg/ml oral solution
Fentanyl 100 mcg injection	Ketamine 50mgml injection	Cyclizine
Fentanyl 500 mcg injection	Diazepam 5mg/ml Injection	Promethazine 10mg tablet
Fentanyl 25 mcg patch	Diazepam 5mg tablet	Promethazine 50mg/2ml injection
Fentanyl 50 mcg patch	Clonazepam 2.5mg/ml oral drops	Movicol - POLYETHYLINE GLYCOL
Fentanyl 100 mcg patch	Haloperidol 5mg tablet	Phenytoin

Fentanyl 100 mcg sublingual tablet	Amitriptyline 10 and 25mg tablet	Carbamazepine
Codeine phosphate 30mg tablet	Ondansetron 2mg/ml injection	Lamotrigine
Tylenol III (Acetaminophen 300mg & codeine 30mg)	Ondansetron 8 mg tablet	Olanzapine
Tramadol 100mg injection	Glycopyrronium 1mg tablet	Lidocane 5% patches
Tramadol 50mg tablet	Hyoscine hydropromide 400mcg/1ml injection	Methylnaltrexone
Tramadol 100mg tablet	Sodium Valproate 200mg/5ml elixir	Spironolactone
Naloxone 0.4mg/ml injection	Scopolamine 1.5mg patch	EMLA cream
Acetaminophen 500mg tablet	Methylphenidate 20mg tablet	
Ibuprofen 400mg tablet	Atropine 600mcg/ml injection	
Midazolam 15mg/3ml injection	Diclofenac topical cream	
Lorazepam 1mg tablet		
Atropine eye drops 1%		
Benztropine 2mg/2ml injection		
Dexamethasone 8mg/2ml injection		
Dexamethasone 8mg tablet		
Prednisone 10mg tablet		
Hyrdocortisone cream		
Haloperidol 5mg/ml injection		
Octreotide 100mcg/ml injection		
Hyoscine butylbromide 20mg/1ml injection		
Glycopyrronium 200mcg/ml injection		
Metoclopramide 10mg/2ml injection		
Metoclopramide 10mg tablet		
Diphenhydramine 25mg tablet		
Diphenhydramine 25mg injection		
Bisacodyl 5mg tablet		
Bisacodyl 10mg suppositories		
Docusate sodium 100mg capsules		
Senna 8mg tablet		
Lactulose solution		
Glycerine suppositories		
Fleet enema		
Loperamide 2mg capsules		
Nystatin 100,000 units/ml oral liquid		
Pregabalin 50mg and 150mg capsules		
Gabapentin 300mg and 800mg capsules		
Levetiracetam 500mg tablet		
Levetiracetam 100mg/ml syrup		
Levetiracetam 100mg/ml injection		
Modafinil 100mg tablet		
Megestrol		
Escitalopram 10mg tablet		
Mertazapine 30mg tablet		
Baclofen 10mg tablet		
Furosemide 40mg tablet		
Furosemide 10mg/ml		
Bisphosphonate (Zoledronic acid, Pamidronate)		
Vitamin D and Calcium		

The frequency was considered mandatory by 70% of the participants. The list of medications reported as "Mandatory" but less frequently (20% of the participants), including modafinil 100mg tablets, megestrol, and fentanyl 500mcg injections, as shown in (Table 2). The "Necessary" medication list including the following: modafinil 100 mg tablet (recommended by 60% of the participants), morphine (SR) 60mg tablet (50%), megestrol (50%), and prednisone 10mg tablet (40%), as shown in (Table 2). For "Optional" medications, the percentage of participants who recommended fentanyl 500 mcg injections was 50%; hydrocortisone cream, 50%; and atropine eye drops, 1% was 40%.

Discussion

The primary objective of this project was to explore the degree of consensus among physicians involved in palliative care (PC) regarding appropriate pharmacological treatment for common symptoms of palliative patients with cancer and to thus develop a national medication list of essential medicines for PC based on expert opinion. Saudi Arabia is the largest state in Western Asia with an area of more than 2 million km^2; Palliative care in Saudi Arabia is still in its nascent stages. Even after two decades, palliative care is not widely available across Saudi Arabia [15]. Meanwhile, the Ministry of Health (MOH) launched the Last Phase Initiative as part of the Transformation of Healthcare - Vision 2030. One of that initiative was to have national palliative care guideline to standardize the practice, where it was launched in 2018. Different palliative care physicians and nursing graduates from 16 different countries where the treat and dispense different medication due to different backgrounds practice. Also, the Medication Supply chain, drugs list in MOH wasn't include the different the majority of Narcotics medication. Even more, it didn't include the different form and strength of medication. Many patients receiving palliative care wish to remain at home for as long as possible. To help achieve this aim, they need rapid access to medicines to provide symptom relief. Such palliative care narcotics national medication list protocols support health professionals in the practice of handling and administering medicine to palliative care patients in tertiary, secondary hospitals or even living at home.

The research was attended by leading palliative consultants' specialists in the Kingdom of Saudi Arabia, with a high degree of agreement among experts. More than 60 drugs have been used in the study. Preference for prescription was divided into three categories-mandatory, appropriate, and optional-based on the frequency of administration and the categories listed. "mandatory" medicines such as baclofen pills, loperamide, ibuprofen tablets, midazolam injections, Tylenol III and opioid injections, morphine injections, morphine (IR) syrup, and morphine (SR). This list will serve as a key for future decision making in clinical practice. We found a high level of consensus among the clinical PC experts about the EML and the "Mandatory," "Essential," and "Optional" Optional categories. More than 60 medications were reviewed and categorized by experts from different organizations. A recommendation based on a broad consensus-not only of the opinions resulting from this study, but also of the opinions supported by other existing documentation-will have great implications for changes in policy, education, and research, and may influence legislation and drug availability. Based on our findings, few medications, such as fentanyl and morphine midazolam, hyoscine butyl bromide, loperamide, haloperidol, hyoscine butyl bromide, docusate sodium, and acetaminophen, have been reported as frequently prescribed medications to PC patients, which corresponds with the WHO EML [16].

Drugs administered and identified in this study can be integrated into the WHO EML, which, in turn, may lead to a constructive improvement in municipal drug policy and provide the basis for a basic level of treatment for PC institutions. The main limitations are the lack of a pre-existing national PC medication list, flexibility within a defined framework, and various methods for different specialty practices. The number of doctors in our hospital, as well as whether or not they are effective members. Doctors' desire to distinguish their beliefs from their practices. If their experience differs from the national registry, even if they work outside of specialized PC environments. However, assessing the efficacy of an intervention over time can alleviate the burden of these limitations, especially in continuous improvement.

Conclusion

The medications prescribed and identified in this study should be integrated into the WHO EML, which may lead to a positive shift in local drug policies and serve as the foundation for minimum standards for PC institutions. Based on this consensus, other current recommendations, and taking into account all variations in local care traditions and drug availability. Our recommendations are that the medications used in the EML be made available in all settings caring for palliative patients, including those outside of specialist PC settings, in order to close the knowledge-practice gap. The PC guidelines listed in the previous list need to be revised. The central committee recommended that the Kingdom's top PC experts prepare a review of available evidence in support of the development of an EML for PC to ensure access to appropriate medicines for the pharmacological management of the most distressing symptoms of adult patients in KSA with life-threatening and life-limiting conditions.

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