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Cancer Management in Saudi Arabia: Recommendations by the Saudi Oncology HeAlth Economics ExpeRt GrouP (SHARP)

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ABSTRACT

Cancer is widely recognized as a major global health problem and is estimated to rank as one of the leading causes of death worldwide. Saudi Arabia has undergone remarkable socioeconomic development in the past 40 years which has contributed to the increase in cancer incidence. The high costs of new oncology medications in combination with uncertainty of long-term effectiveness and safety outcomes highlight the importance of considering value, in terms of clinical outcomes, relative to cost. We convened a group of experts to discuss key factors impacting the current state of cancer management in Saudi Arabia and to agree on a list of recommendations, with a focus on value-based care, considering evidence, patients, and costs.
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Recommendations by the Saudi Oncology HeAlth Economics ExpeRt GrouP (SHARP). This table is summarizing the key recommendations of the SHARP expert group. Four main domains were discussed including regulatory, procurement, treatment, and patients.

1. Regulatory Domain

- Registration of oncology medications:
  - ○ Develop a special pathway involving accelerated timelines and providing market exclusivity to enforce and incentivize the registration of essential/old oncology medications.
  - ○ Assess the need for a preliminary approval pathway that could accelerate the registration process of novel agents when limited data is presented.
  - ○ Publish an updated report regarding drugs under review and registration status to the public.
- Conduct of clinical trials:
  - ○ Establishment of a national cancer research consortium that develops policies and collaborative protocols among different institutions to streamline processes and accelerate

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regulatory approvals.

○ Connect the institutions, especially in peripheral areas, with clinical trials experts to ease the burden of conducting research and enhance the recruitment process.

○ Raise awareness among patients and their families regarding the importance of clinical trials in oncology treatment to improve the participation rates.

2. Procurement Domain

• Impact of procurement on access to medications:

○ Create an institution-based oncology formulary, supported by the most updated evidence and practice needs and benchmarks.

○ Update the oncology formularies regularly to secure the needed medications and reduce possible waste.

○ Hospitals should have robust systems in place for forecasting medication supply and demand to avoid delays or shortages and communicate with procurement companies.

○ Creating a mechanism/pathway whereby essential medications have an accelerated process for procuring.

• Adoption of value-based care:

○ Education of healthcare practitioners and key stakeholders about value-based care concept.

○ Work closely with patients to validate culturally tailored Arabic PRO tools.

○ Develop value-based practice guidelines for Saudi oncology patients to ensure unified and fair access to essential medications.

3. Treatment Domain

• Benefits of standalone oncology pharmacy and therapeutics (P&T) subcommittees:

○ Encourage institutions to establish standalone oncology P&T subcommittees that includes experts from a range of disciplines, e.g., oncologist, nurse, oncology pharmacist, palliative care specialist, and pharmacoeconomics.

• Adaptation of precision medicine in hospital settings

○ Establishment of centralized labs that serve providers nationwide and preforms highly sophisticated personalized testing in a unified and timely manner.

4. Patients Domain

• The role of patient advocacy groups in improving patient experience and understanding of cancer treatment:

○ Support oncology advocacy groups by engaging oncology experts and cancer survivors in educating the public on treatment options, the benefit/risk profile of medications, and the eligibility criteria for use of medications.

○ Comprehensive information of cancer treatment should be made available to the general public in layman-friendly language.

○ Engage advocacy groups in the clinical decision-making process by developing communication channels between patient advocacy groups and official bodies.

○ Healthcare providers can capitalize on the advanced technology and reach out to patients via a range of social media platforms to educate patients as well as raise awareness of diagnostic screening tests.

1. Introduction

Cancer is widely recognized as a major global health problem and is estimated to rank as one of the leading causes of death worldwide. Significant progress has been made in recent years in relation to the prevention and treatment of certain cancers (Fitzmaurice et al., 2015). Nevertheless, the burden of cancer is increasing. It is estimated that 18.1 million new cancer cases and 9.6 million cancer deaths occurred globally in 2018 (Bray et al., 2018). The high prevalence of cancer has been attributed to many risk factors, several of which are associated with lifestyle and socioeconomic factors (e.g., smoking, obesity, and physical inactivity). Saudi Arabia has undergone remarkable socioeconomic development in the past 40 years; during this societal drift, the population lifestyle has also been modified, and this has contributed to the increase in cancer incidence (Althubiti and Nour Eldein, 2018). A total of 17,602 new cancer cases was reported by the Saudi Cancer Registry (SCR) in 2016 and its predicated to reach 39,869 new cases by 2030 (Ferlay et al., 2018; Saudi Health Council, 2016). Were breast and colorectal cancer reported among the most common types in Saudi Females and Males, respectively.

In parallel with the rapid growth of cancer incidence, the associated economic burden is also rising. This is largely due to pharmaceutical expenditure, which is the most burdensome component of overall healthcare spending in many countries (Adamski et al., 2010; Navarria et al., 2015; Zaric and Xie, 2009). Oncology is one of the therapeutic areas that has seen the most rapid rise in spending, growing up to 21% per annum in recent years (McCabe et al., 2009), largely due to the launch of new high-cost therapies. However, expensive treatments do not necessarily equate to improved outcomes, as previous research has demonstrated (Abboud et al., 2013). Healthcare payers are often under pressure to make as early decisions as the time of product launch, when the available evidence can be limited, including scarce information about the performance of the product outside the controlled clinical trial setting.

The high costs of new oncology medications in combination with uncertainty of long-term effectiveness and safety outcomes highlight the importance of considering value, in terms of clinical outcomes, relative to cost. In light of this, the Saudi Ministry of Health (MOH) has recently adopted a patient-centric value-based approach to healthcare, aimed at balancing the clinical benefits versus costs when making decisions related to drug reimbursement. A group of experts were convened to discuss key factors impacting the current state of cancer management in Saudi Arabia and to agree on a list of recommendations, with a focus on value-based care, considering evidence, patients, and costs.

2. Methods

The Saudi Oncology HeAlth Economics ExpeRt GrouP (SHARP), along with a cancer patient representative, were convened in December 2019 for a 2-day focus group meeting to discuss cancer management in Saudi Arabia, with a long-term vision to improve cancer patient care and quality of life. SHARP consists of a group of oncology physicians, oncology pharmacists, representatives from the Saudi Food and Drug Administration (SFDA), the National Unified Procurement Company (NUPCO), and pharmacoeconomists. Focus group discussions were held to discuss challenges and recommendations on the following four key domains that can impact cancer care: regulatory, procurement, treatment and patient domains. Group discussions were conducted in accordance with guidelines on focus group research (Richard A. Krueger; Mary Anne Casey, 2014). Discussions were led and moderated by research facilitators. This article summarizes the topics discussed under each domain and key recommendations.

3. Results

3.1. Challenges and recommendations for cancer management in Saudi Arabia

3.1.1. Regulatory domain

3.1.1.1. Registration of oncology medications. The Saudi Food and Drugs Administration (SFDA) was established in 2003 to regulate the access to safe and effective drug products and medical devices (SFDA, 2008). Drug evaluation and registration is conducted by the drug sector employees and a committee of independent experts. The registration application submitted by market authorization applicants (MAA) must meet data requirements with sufficient level of evidence. However, a handful of essential and early agents are available in the market but not yet registered. The non-registered status of such agents can limit the access, easiness of pharmacovigilance reporting, and hinder the continuity and quality of care provided to cancer patients. MMA's have to be mandated to register these agents. Currently, SFDA offers a priority registration pathway for products with shortages or unmet needs when prior approval exists. Expanding the fast-track registration pathway to include essential oncological agents is an important step toward improving the access and regulation of those agents. Secondly, SFDA has developed an administrative document detailing the regulatory framework for drug approvals to stakeholders (SFDA, 2008). Missing or unjustified information submitted by pharmaceutical companies when applying for registration might delay the process. Thus, MAA's have to work closely with SFDA in order to submit complete and accurate information to prevent further delays in the registration process. Additionally, delayed approval process may occur when there are limitations in the evidence from clinical trials i.e. lack of comparator arm or suboptimal endpoints. Thus, implementing a preliminary approval status, that can be granted to oncological agents in such scenarios, might help in accelerating the availability without limiting the SFDA capacity to conduct a comprehensive due diligence before approving the drug.

3.1.1.1.1. Key recommendations.

- Develop a special pathway involving accelerated timelines and providing market exclusivity or competitive price to incentivize the registration of essential/old oncology medications.
- Assess the need for a preliminary approval pathway that could accelerate the registration process of novel agents when limited data is presented.
- Publish an updated report regarding drugs under review and registration status to the public.

3.1.1.2. Conducting clinical trials. Clinical trials are not frequently conducted in the Arab World including Saudi Arabia. A recent *meta*-analysis examining approved oncological agents evaluated in international Phase III Clinical Trials revealed that only Egypt was included in two studies (AlHashem et al., 2016). This is despite the fact that The Arab World comprises around 422 million people, approximately 6% of the global population (Yoruk and Tetik, 2014). Conducting clinical trials in the region is important in order to assess clinical efficacy and safety of medications in the specific population since the response to these agents can be influenced by genetics, demographics, and other lifestyle factors (ref). Additionally, participation in clinical trials is one mean of obtaining earlier access to new and novel agents. Exclusion of The Arab World from clinical research may be due to the lack of collaborative infrastructure, awareness of available regulations, and economic factors.

In Saudi Arabia, the SFDA regulates the registration and monitoring of clinical trials, via the unified Saudi Clinical Trial Application System (SCTR) (SFDA, 2012). The process of clinical trials registration can be lengthy and meticulous, requiring the primary investigator to fill multiple comprehensive documents delineating the study protocol, subjects and sites. Therefore, the absence of clinical research managers (CRM) within the institution and multidisciplinary research teams might limit the ability of applying for clinical trials in the first place. Additionally, when clinical trials are conducted independently they will be limited by small patient numbers and have limited generalizability since the data collected are only reflective of a single institute. Thus, it is imperative to encourage the conduction of multi-center clinical trials; however, they are limited by the lack well-defined research agreements between hospitals, insufficient research personnel, overloaded physicians, and concerns about recruiting sufficient numbers of patients considering the limited awareness. Establishing an oncology-focused collaborative research consortium that is connected to all stakeholders and supported by the regulators, in order to create policies, accelerate the approvals, streamline the process, is thought to improve clinical research quality and enhance recruitment.

3.1.1.2.1. Key recommendations.

- Establishment of a national cancer research consortium that develops policies and collaborative protocols among different institutions to streamline processes and accelerate regulatory approvals.
- Connect the institutions, especially in peripheral areas, with clinical trials experts to facilitate conducting research and enhance the recruitment process.
- Raise awareness among patients and their families regarding the importance of clinical trials in oncology treatment to improve the participation rates.

3.2. Procurement domain

3.2.1. Impact of procurement on access to medications

Procurement policies play an important role in improving access to medications. In Saudi Arabia, there are different pathways in place for the procurement of formulary and non-formulary medications (Alrasheedy et al., 2017). The National Unified Procurement Company (NUPCO) for Medical Supplies was created to curtail the pharmaceutical expenditures (NUPCO, 2020). NUPCO is currently handling government tenders, facilitate procurement and distribution of medications, and bundling procurement orders. Healthcare institutions have to create effective measures and proactive plans in order to maximize the benefit of public procurement. Thus, establishing oncology formularies within institutions and updating it periodically to secure needed quantities and reduce possible waste. For example, in the MOH, a unified central formulary was created, of which there are normally no shortages or delays (Ahmed Alomi et al., 2019). On the other hand, the process of procurement of non-formulary medications could take 3 to 6 months to secure it. Unfortunately, sometimes patients do not get the chance to receive a non-formulary medication, as they may succumb due to their illness or have a progression of their disease. The timescale depends on number of factors including; level of demand, medications stock, registration status, cost and financial approval by purchasing departments then approval by customs and SFDA.

3.2.1.1. Key recommendations.

- Create an institution-based oncology formulary, supported by the most updated evidence and practice needs.
- Update the oncology formularies regularly to secure the needed medications and reduce possible waste.

- Hospitals should have robust systems in place for forecasting medication supply and demand to avoid delays or shortages and communicate with procurement companies.
- Creating a mechanism/pathway whereby essential medications have an accelerated process for procuring.

3.2.2. Adoption of value-based care

Some health institutions in Saudi Arabia are in the process of shifting from traditional care to value-based care, involving the adoption of value-based procurement agreements. Value-based agreements are type of reimbursement scheme between payers and medical product manufacturers that have proven to be a useful tool in addressing increasing cost pressures, uncertain effectiveness, and ensuring value in healthcare decision-making (Navarria et al., 2015). Such agreements differ from the traditional financial-based schemes, which are purely expenditure focused such as price–volume agreements and discounts (Yoruk and Tetik, 2014). Value-based agreements place emphasis on product performance, and the amount or nature of reimbursement is based on actual clinical outcomes achieved (Dunlop et al., 2018). Such schemes help to accelerate patient access to medications. In 2019, MOH established 5 value-based agreements with pharmaceutical manufacturers. Despite the adoption of such agreements in Saudi Arabia, many healthcare professionals in the country are still not familiar with the concept and have limited understanding of these schemes

Additionally, value-based care should consider patient experience, treatment satisfaction, and quality of life. Patient Reported Outcome (PRO) tools are still need to be validated for use in locally. Furthermore, local clinical practice guidelines for oncology patients are needed to improve value-based care (Bazarbashi, 2011). The existence of such guidelines would help ensure the access to essential medications, as well as provide treatment-equity among patients – ensuring all patients have the same treatment options.

3.2.2.1. Key recommendations.

- Education of healthcare practitioners and key stakeholders about value-based care concept.
- Work closely with patients to validate culturally tailored Arabic PRO tools.
- Develop value-based practice guidelines for Saudi oncology patients to ensure unified and fair access to essential medications.

3.3. Treatment domain

3.3.1. Benefits of standalone oncology pharmacy and therapeutics (P&T) subcommittees

Establishing a standalone oncology P&T subcommittee within each institution will enable experts and front-line staff, who have a good understanding of patient experiences and outcomes, to contribute to the decision-making process. These subcommittees would oversee all issues pertaining to oncological agents, including clinical and economic evaluations and creating institution specific prescribing guidelines and protocol guidelines. However, this may pose a challenge as certain experts such as pharmacoeconomists are scarce in the country.

3.3.1.1. Key recommendations.

- Encourage institutions to establish standalone oncology P&T subcommittees that includes experts from a range of disciplines, e.g. oncologist, nurse, oncology pharmacist, palliative care specialist, and pharmacoeconomists.

3.3.2. Adaptation of precision medicine in hospital settings

As mentioned earlier, creating local clinical guidelines is an essential step toward ensuring the implementation of evidence-based medicine within institutions. These guidelines can be utilized by oncology P&T committees to facilitate the access to new agents and refine the treatment options for value-based care and procurement process. The current evolving evidence in cancer therapeutics are heavily revolving around the adaptation of a precision medicine approaches. Precision medicine involves tailoring treatment plans based on the characteristics of individual patient multiomic profile (Bazarbashi, 2011; Ciardiello et al., 2014; Levit et al., 2019). Early adaptation of precision medicine, when treating oncology patients prevents the use of unnecessary highly toxic oncological agents and eventually reduce the economic burden of cancer treatment. Limited and scattered resource (laboratories and scientists) and difficulty to access to diagnostic tests (genetic tests, next-generation sequencing), is a current struggle worldwide and within Saudi Arabia. Collaboration between governmental sectors is needed to establish a centralized and highly specialized diagnostic laboratories in Saudi Arabia, in order to improve access to diagnostic tests and unify the resources. The benefits of having a centralized, validated, and standardized laboratory is that testing methodology will be standardized and thus results from different hospitals will be comparable; this will also be beneficial for the purpose of clinical research.

3.3.2.1. Key recommendations.

- Establishment of centralized labs that serve providers nationwide and preforms highly sophisticated personalized testing in unified and timely manner.

3.4. Patients domain

3.4.1. The role of patient advocacy groups in improving patient experience and understanding of cancer treatment

Patient advocacy groups around the world works closely with leading oncology organizations to uplift the current management of cancer patients by providing education and support of cancer survivors, patients, and caregivers (ASCO, 2020; ESMO, 2020; Schear et al., 2015). In the Kingdom, there are several well-established cancer advocacy groups. Patient advocacy groups are normally well informed and keep up-to-date with the latest drug developments. One oncology patient advocacy group in Riyadh, was established by a cancer survivor; and now made up of around 230 cancer survivors as well as a few oncologists. The purpose of it is to educate patients and provide support and recommendations regarding medication use and safety. Thus, the participation of oncology experts in educating patient advocacy groups representatives is vital to provide reliable sources of information and prevent using misleading information from the family members, community, and the internet. Comprehensive information on medications, including approved indications, eligibility criteria, etc. should be made available to the general public in layman-friendly language.

A patient-centric approach to healthcare is critical in enhancing clinical outcomes and quality of life; this approach includes involvement of patients in their own care and clinical decision-making process. It is essential for oncology experts to educate and engage in dialogue with patient advocacy groups. Ideally, patient advocacy groups for cancer should be split according to the type of cancer, to allow for indication-specific education. Patients should be educated on treatment options, the benefit/risk profile of medications, the eligibility criteria for use of medications, navigating the available clinical trials option, and end of life care. This will equip patients with the tools to make informed decisions based on scientific evidence.

On the other hand, advocacy groups have an essential role in helping healthcare providers and regulators to understand the

needs, wishes, concerns, and priorities of oncology patients, survivors, and caregivers. Supporting the implementation of effective value-based procurement models, enhance cancer care, and direct patient centered clinic research. Additionally, these groups can build a stronger community bond by strengthen patient's autonomy, support patient rights, and collect financial support for patients in need. Communication channels between patient advocacy groups and official bodies, such as the SFDA and MOH. Patients should be involved in the decision-making process at each level, including at the level of drug approval. In some cases, clinical evidence is equivocal, and it is necessary to listen to the patient voice – to understand patient experience and opinion - in order for a decision to be made with regards to drug approval.

3.4.1.1. Key recommendations.

- Support oncology advocacy groups by engaging oncology experts in educating the public on treatment options, the benefit/risk profile of medications, and the eligibility criteria for the use of medications.
- Comprehensive information cancer treatment should be made available to the general public in layman-friendly language.
- Engage advocacy groups in the clinical decision-making process by developing communication channels between patient advocacy groups and official bodies.
- Healthcare providers can capitalize on the advanced technology in the Kingdom and reach out to patients via a range of social media platforms to educate patients as well as raise awareness of diagnostic screening tests.

4. Conclusion

This article outlines recommendations from SHARP pertaining to 4 key domains that impact cancer care: regulatory, procurement, treatment and patient domains. These recommendations were aligned with the Saudi Vision 2030, to optimize cancer management in a multi-level multidisciplinary approach, with a focus on value-based care that places central importance on patient outcomes.

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Declaration of Competing Interest

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References

Abboud, C., Berman, E., Cohen, A., Cortes, J., DeAngelo, D., Deininger, M., Devine, S., Druker, B., Fathi, A., Jabbour, E., Jagasia, M., Kantarjian, H., Khoury, J., Laneuville, P., Larson, R., Lipton, J., Moore, J.O., Mughal, T., O'Brien, S., Pinilla-Ibarz, J., Quintas-Cardama, A., Radich, J., Reddy, V., Schiffer, C., Shah, N., Shami, P., Silver, R.T., Snyder, D., Stone, R., Talpaz, M., Tefferi, A., Van Etten, R.A., Wetzler, M., Abruzzese, E., Apperley, J., Breccia, M., Byrne, J., Cervantes, F., Chelysheva, E., Clark, R.E., De Lavallade, H., Dyagil, I., Gambacorti-Passerini, C., Goldman, J., Haznedaroglu, I., Hjorth-Hansen, H., Holyoake, T., Huntly, B., Le Coutre, P., Lomaia, E., Mahon, F.X., Marin-Costa, D., Martinelli, G., Mayer, J., Milojkovic, D., Olavarria, E., Porkka, K., Richter, J., Rousselot, P., Saglio, G., Saydam, G., Stentoft, J., Turkina, A., Vigneri, P., Zaritskey, A., Aguayo, A., Ayala, M., Bendit, I., Bengio, R. M., Best, C., Bullorsky, E., Cervera, E., Desouza, C., Fanilla, E., Gomez-Almaguer, D., Hamerschlak, N., Lopez, J., Magarinos, A., Meillon, L., Milone, J., Moiraghi, B., Pasquini, R., Pavlovsky, C., Ruiz-Arguelles, G.J., Spector, N., Arthur, C., Browett, P., Grigg, A., Hu, J., Huang, X. jun, Hughes, T., Jiang, Q., Jootar, S., Kim, D.W., Malhotra, H., Malhotra, P., Matsumura, I., Melo, J., Ohnishi, K., Ohno, R., Saikia, T., Schwarer, A.P., Takahashi, N., Tam, C., Tauchi, T., Usuki, K., Wang, J., Abdel-Rahman, F., Aljurf, M.D.S., Bazarba-Chi, A., Yehuda, D. Ben, Chaudhri, N., Durosinmi, M., Kamel, H., Louw, V., Matti, B.F., Nagler, A., Raanani, P., Salem, Z., 2013. The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: From the perspective of a large group of CML experts. Blood 121, 4439–4442. https://doi.org/10.1182/blood-2013-03-490003.

Adamski, J., Godman, B., Ofierska-Sujkowska, G., Osiska, B., Herholz, H., Wendykowska, K., Laius, O., Jan, S., Sermet, C., Zara, C., Kalaba, M., Gustafsson, R., Garuolienè, K., Haycox, A., Garattini, S., Gustafsson, L.L., 2010. Risk sharing arrangements for pharmaceuticals: Potential considerations and recommendations for European payers. BMC Health Serv. Res. 10. https://doi.org/10.1186/1472-6963-10-153.

Ahmed Alomi, Y., Jamaan Alghamdi, S., Abdullah Alattyh, R., 2019. IJPHS International Journal OF Pharmacy and Health Sciences National Pharmacy Inventory Management System at the Ministry of Health Institutions in Saudi Arabia. Int. J. Pharm. Heal. Sci. 2. https://doi.org/10.5530/ijphs.2019.1.2.

AlHashem, H.Y., Al-Mubarak, M., Vera-Badillo, F.E., Templeton, A.J., Ocana, A., Seruga, B., Amir, E., 2016. Impact of Geographic Region on Benefit of Approved Anticancer Drugs Evaluated in International Phase III Clinical Trials. Clin. Oncol. 28, 283–291. https://doi.org/10.1016/j.clon.2015.09.010.

Alrasheedy, A.A., Hassali, M.A., Wong, Z.Y., Aljadhey, H., Karamah Al-Tamimi, S., Saleem, F., 2017. Pharmaceutical policy in Saudi Arabia. In: Pharmaceutical Policy in Countries with Developing Healthcare Systems. Springer International Publishing, pp. 329–347. https://doi.org/10.1007/978-3-319-51673-8_16.

Althubiti, M.A., Nour Eldein, M.M., 2018. Trends in the incidence and mortality of cancer in Saudi Arabia. Saudi Med. J. 39, 1259–1262. https://doi.org/10.15537/smj.2018.12.23348.

ASCO, 2020. Patient Advocates [WWW Document]. URL https://www.asco.org/membership/member-benefits/patient-advocates (accessed 4.1.20).

Bazarbashi, S., 2011. Why local guidelines?. Urol. Ann. 3, 1. https://doi.org/10.4103/0974-7796.78547.

Bray, F., Ferlay, J., Soerjomataram, I., Siegel, R.L., Torre, L.A., Jemal, A., 2018. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA. Cancer J. Clin. 68, 394–424. https://doi.org/10.3322/caac.21492.

Ciardiello, F., Arnold, D., Casali, P., Cervantes, A., Douillard, J., Eggermont, A., Eniu, A., McGregor, K., Peters, S., Piccart, M., Popescu, R., Van Cutsem, E., Zielinski, C., Stahel, R., 2014. Delivering precision medicine in oncol-ogy today and in future-the promise and challenges of personalised cancer medi-cine: a position paper by the European Society for Medical Oncology (ESMO) defining personalised cancer medicine. https://doi.org/10.1093/annonc/mdu217.

Dunlop, W.C.N., Staufer, A., Levy, P., Edwards, G.J., 2018. Innovative pharmaceutical pricing agreements in five European markets: A survey of stakeholder attitudes and experience. Health Policy (New. York) 122, 528–532. https://doi.org/10.1016/j.healthpol.2018.02.008.

ESMO, 2020. Patient Advocates [WWW Document]. URL https://www.esmo.org/for-patients/patient-advocates-working-group (accessed 4.1.20).

Ferlay, J., Ervik, M., Lam, F., Colombet, M., Mery, L., Piñeros, M., Znaor, A., Soerjomataram, I., Bray, F., 2018. Global Cancer Observatory: Cancer Tomorrow. World Heal Organ.

Fitzmaurice, C., Dicker, D., Pain, A., Hamavid, H., Moradi-Lakeh, M., MacIntyre, M.F., Allen, C., Hansen, G., Woodbrook, R., Wolfe, C., Hamadeh, R.R., Moore, A., Werdecker, A., Gessner, B.D., Te Ao, B., McMahon, B., Karimkhani, C., Yu, C., Cooke, G.S., Schwebel, D.C., Carpenter, D.O., Pereira, D.M., Nash, D., Kazi, D.S., De Leo, D., Plass, D., Ukwaja, K.N., Thurston, G.D., Yun Jin, K., Simard, E.P., Mills, E., Park, E.K., Catalá-López, F., DeVeber, G., Gotay, C., Khan, G., Hosgood, H.D., Santos, I.S., Leasher, J.L., Singh, J., Leigh, J., Jonas, J.B., Sanabria, J., Beardsley, J., Jacobsen, K.H., Takahashi, K., Franklin, R.C., Ronfani, L., Montico, M., Naldi, L., Tonelli, M., Geleijnse, J., Petzold, M., Shrime, M.G., Younis, M., Yonemoto, N., Breitborde, N., Yip, P., Pourmalek, F., Lotufo, P.A., Esteghamati, A., Hankey, G.J., Ali, R., Lunevicius, R., Malekzadeh, R., Dellavalle, R., Weintraub, R., Lucas, R., Hay, R., Rojas-Rueda, D., Westerman, R., Sepanlou, S.G., Nolte, S., Patten, S., Weichenthal, S., Abera, S.F., Fereshtehnejad, S.M., Shiue, I., Driscoll, T., Vasankari, T., Alsharif, U., Rahimi-Movaghar, V., Vlassov, V. V., Marcenes, W.S., Mekonnen, W., Melaku, Y.A., Yano, Y., Artaman, A., Campos, I., MacLachlan, J., Mueller, U., Kim, D., Trillini, M., Eshrati, B., Williams, H.C., Shibuya, K., Dandona, R., Murthy, K., Cowie, B., Amare, A.T., Antonio, C.A., Castañeda-Orjuela, C., Van Gool, C.H., Violante, F., Oh, I.H., Deribe, K., Soreide, K., Knibbs, L., Kereselidze, M., Green, M., Cardenas, R., Roy, N., Tillmann, T., Li, Y., Krueger, H., Monasta, L., Dey, S., Sheikhbahaei, S., Hafezi-Nejad, N., Kumar, G.A., Sreeramareddy, C.T., Dandona, L., Wang, H., Vollset, S.E., Mokdad, A., Salomon, J.A., Lozano, R., Vos, T., Forouzanfar, M., Lopez, A., Murray, C., Naghavi, M., 2015. The Global Burden of Cancer 2013. JAMA Oncol. https://doi.org/10.1001/jamaoncol.2015.0735.

Levit, L.A., Kim, E.S., McAneny, B.L., Nadauld, L.D., Levit, K., Schenkel, C., Schilsky, R. L., 2019. Implementing precision medicine in community-based oncology programs: three models. J. Oncol. Pract. 15, 325–329. https://doi.org/10.1200/jop.18.00661.

McCabe, C., Bergmann, L., Bosanquet, N., Ellis, M., Enzmann, H., von Euler, M., Jönsson, B., Kallen, K.-J., Newling, D., Nüssler, V., Paschen, B., de Wilde, R., Wilking, N., Teale, C., Zwierzina, H., Biotherapy Development Association, 2009. Market and patient access to new oncology products in Europe: a current, multidisciplinary perspective. Ann. Oncol. Off. J. Eur. Soc. Med. Oncol. 20, 403–12. https://doi.org/10.1093/annonc/mdn603.

Navarria, A., Drago, V., Gozzo, L., Longo, L., Mansueto, S., Pignataro, G., Drago, F., 2015. Do the current performance-based schemes in Italy really work? «Success

fee»: A novel measure for cost-containment of drug expenditure. Value Heal. 18, 131–136. https://doi.org/10.1016/j.jval.2014.09.007.
NUPCO, 2020. The National Unified Procurement Company [WWW Document]. URL https://www.nupco.com/en/our-services/unified-procurement/ (accessed 4.1.20).
Richard A. Krueger; Mary Anne Casey, 2014. Casey - Focus Groups_ A Practical Guide for Applied Research. SAGE Publications Ltd.
Saudi Health Council, 2016. Cancer incidence report in Saudi Arabia 2016.
Schear, R.M., Manasco, L., McGoldrick, D., Kajana, K., Rosenthal, L., McMikel, A., Lins, N., 2015. International framework for cancer patient advocacy: empowering organizations and patients to create a national call to action on cancer. J. Glob. Oncol. 1, 83–91. https://doi.org/10.1200/jgo.2015.000398.
SFDA, 2012. Guidance to use Saudi Clinical Trail Registry (SCTR).
SFDA, 2008. Regulatory Framework for Drugs Approval.
Yoruk, S., Tetik, E., 2014. Challenges and opportunities for clinical research in the Middle East. Appl. Clin. Res. Clin. Trials Regul. Aff. 1, 83–87. https://doi.org/10.2174/2213476x01666140421195221.
Zaric, G.S., Xie, B., 2009. The impact of two pharmaceutical risk-sharing agreements on pricing, promotion, and net health benefits. Value Heal. 12, 838–845. https://doi.org/10.1111/j.1524-4733.2009.00510.x.