Poster #HPR80

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Moving towards inclusion - A review of access to oncology therapies in the light of global efforts to advance gender equality

Perez-Kempner, Lucia
Budhia, Sangeeta

Background

At the center of the United Nation's Sustainable Development Goals (SDGs) is improvement of health and education, alongside equality and, in particular, gender equality (SDG #5). Due to body anatomy, healthcare for males and females differs due to diseases that are gender specifics. This study aimed to analyze if the global agenda for access to novel oncology agents is in line with UN SDG #5 or if gender inequalities persist.

Methods

We selected eight gender-specific cancers of the reproductive system (i.e., male: prostate, penile, testicle cancer; female: cervical, ovarian, uterine, vaginal, vulvar cancer). Subsequently, we identified novel agents first approved in the United States between 2017-2023 and confirmed their marketing authorization statuses in the United Kingdom, Australia, Canada, and Brazil. Subsequently, we analyzed HTA reports for the approved agents in Australia (PBAC), Brazil (CONITEC) Canada (CADTH), United Kingdom (NICE), and United States (ICER). Additionally, we identified clinical trials registered in clinicaltrials.gov since 2017 for these diseases.

ABBREVIATIONS

ANVISA: Agência Nacional de Vigilância Sanitária; CADTH: Canadian Agency for Drugs and Technologies in Health; CONITEC: Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde; EMA: European Medicines Agency; FDA: Food and Drug Administration; HTA: Health technology assessment; ICER: Institute for Clinical and Economic Review; MHRA: Medicines and Healthcare Products Regulatory Agency; NICE: National Institute for Health and Care Excellence; PBAC: Pharmaceutical Benefits Advisory Committee; SDG: Sustainable development goals; TGA: Therapeutic Goods Administration

REFERENCES

- FDA, EMA, MHRA, TGA, Health Canada, and ANVISA drug search databases.
- ICER, NICE, PBAC, CADTH and CONITEC HTA appraisal reports.
- clinialtrials-gov database

Results

We identified four and five drugs approved for female- and male- specific cancers, respectively (**Table 1**). Of those approved for female-specific cancers, two targeted ovarian, one cervical, and one uterine cancer. All drugs for male-specific cancer targeted prostate cancer. The US had the highest number of marketing authorizations compared to other regulatory agencies examined. Within the authorized drugs, most (3 out of 4) had been assessed by the national HTA agencies in the United Kingdom, Australia, and Canada, and none in Brazil (**Table 2**). Only one (niraparib) had been assessed by ICER in the United States (**Table 2**). Furthermore, we identified 399 Phase-III and 1,557 Phase-II trials for the diseases. Of these, 73.2% (Phase III) and 75.3% (Phase II) were in female-specific and 26.8% (Phase III) and 24.73% (Phase II) in male-specific cancers. Most trials focused on cervical (39.0%), prostate (23.4%), ovarian (19.4%) and uterine (14.5%) cancer. This was in line with disease prevalence (with prostate, uterine, ovarian, and cervical cancer having the highest incidence across all analyzed cancer types), but not in line with unmet need (with only chemotherapy being available to treat vaginal, vulvar, testicular, and penile cancer).

Conclusions

This study did not identify gender trends in terms of the registration and HTA appraisal of oncology agents, with prioritizations across tumors being mostly aligned with disease prevalence. However, it identified a trend towards female-specific oncologic agents in clinical trial programs, which is in line with disease prevalence. The findings are in line with the global development agenda towards SDG #5.

Table 1. Approved drugs across cancers of the reproductive system

Organ	Active ingredient	Marketing authorization status					
		FDA	EMA	MHRA	TGA	Health Canada	ANVISA
Cervical	Tisotumab vedotin	✓ Yes	No	No	No	No	No
Endometrial	Dostarlimab	✓ Yes	✓ Yes	✓ Yes	✓ Yes	✓ Yes	✓ Yes
Ovarian	Pafolacianine	✓ Yes	No	No	No	No	No
Ovarian	Niraparib	✓ Yes	✓ Yes	✓ Yes	✓ Yes	✓ Yes	✓ Yes
Prostate	Ga^{68} PSMA-11	✓ Yes	No	✓ Yes	No	No	No
Prostate	Darolutamide	✓ Yes	✓ Yes	✓ Yes	✓ Yes	✓ Yes	✓ Yes
Prostate	Flotufolastat F^{18}	✓ Yes	No	No	No	No	No
Prostate	Piflufolastat F^{18}	✓ Yes	✓ Yes	✓ Yes	No	No	No
Prostate	Relugolix	✓ Yes	✓ Yes	✓ Yes	No	✓ Yes	No

Table 2. HTA appraisals and outcomes of the approved drugs

Organ	Active ingredient	HTA appraisal and outcome				
		ICER	NICE	PBAC	CADTH	CONITEC
Cervical	Tisotumab vedotin	Not Assessed	N/A	N/A	N/A	N/A
Endometrial	Dostarlimab	Not Assessed	Positive	Positive	Negative	Not Assessed
Ovarian	Pafolacianine	Not Assessed	N/A	N/A	N/A	N/A
Ovarian	Niraparib	Positive	Positive	Positive	Positive	Not assessed
Prostate	Ga^{68} PSMA-11	Not Assessed	Not Assessed	N/A	N/A	N/A
Prostate	Darolutamide	Not Assessed	Positive	Positive	Positive	Not assessed
Prostate	Flotufolastat F^{18}	Not Assessed	N/A	N/A	N/A	N/A
Prostate	Piflufolastat F^{18}	Not Assessed	Not assessed	N/A	N/A	N/A
Prostate	Relugolix	Not Assessed	Pending	N/A	Pending	N/A

- **Positive**: Product was assessed by the HTA agency and received positive recommendation.
- **Negative**: Product was assessed by the HTA agency and received negative recommendation.
- **Pending**: Product is currently being assessed by the HTA agency.
- N/A: Not Applicable (Product not registered in the market, as per Table 1).

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