How Delays In Access Are Losing The Battle Against Cancer: The Impact On Patient And Economic Outcomes

HTA146

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BACKGROUND AND OBJECTIVE

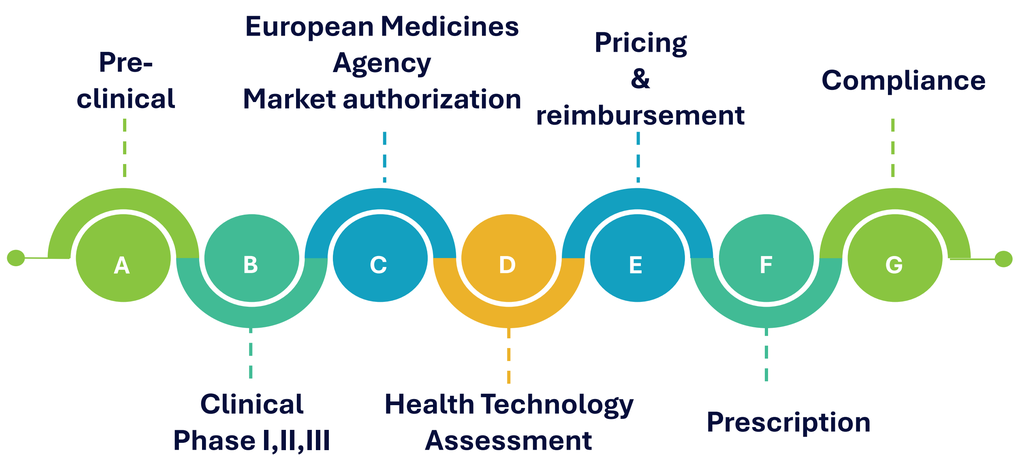
- Cancer is a leading cause of death, with the World Health Organization (WHO) predicting over 35 million new cases by 2050. Thanks to recent scientific advances, many new treatments have been developed that can improve overall survival (OS), prolong time to tumor progression (TTP), or decrease the chance of recurrence of cancer[1] (**Fig. 1**).
- In 2023 alone, the Committee for Medicinal Products for Human Use (CHMP) gave positive opinions to 25 new cancer medicines, which represents one third of all the new medicines reviewed positively by European Medicines Agency (EMA)[2]. However, despite rapid advancements in treatments, delays in accessing cancer treatments remain. This is due in part to the numerous steps of health technology assessment (HTA) agencies resulting in hampered outcomes, such as potential life years (LY) lost, quality-adjusted life years (QALY) lost, and increased economic burden on patients and healthcare systems (**Fig. 2**).
- In 2001, right to health was expanded to ensure that all people have access to healthcare. No matter where they live, people should be able to get quality and affordable health care when they need it[3]. However, in practice, there exists considerable disparity in the speed of access and availability of new drugs after regulatory approval across different countries which conflicts with the right to health.
- This study summarizes literature reporting health and economic impact of delayed access to oncological treatments to patients.

Figure 1: Advantages of new advanced treatments

METHODS

- A targeted review was conducted in PubMed to identify literature published in English from January 2014 to January 2024. A desk search from January 2024 to May 2024 to identify additional grey literature search was also conducted*.
- Search keywords included: Neoplasm, cancer, malignan, oncology, carcinoma, access, reimbursement, approval, regulatory, funding, delay, economic evaluation, cost, cost-analysis, life years, QALY, PFS gain, health impact, quality of life etc.

Figure 2: Steps involved in the access of new treatments to patients in Europe



Adapted from: Ades et al, 2014 [4]

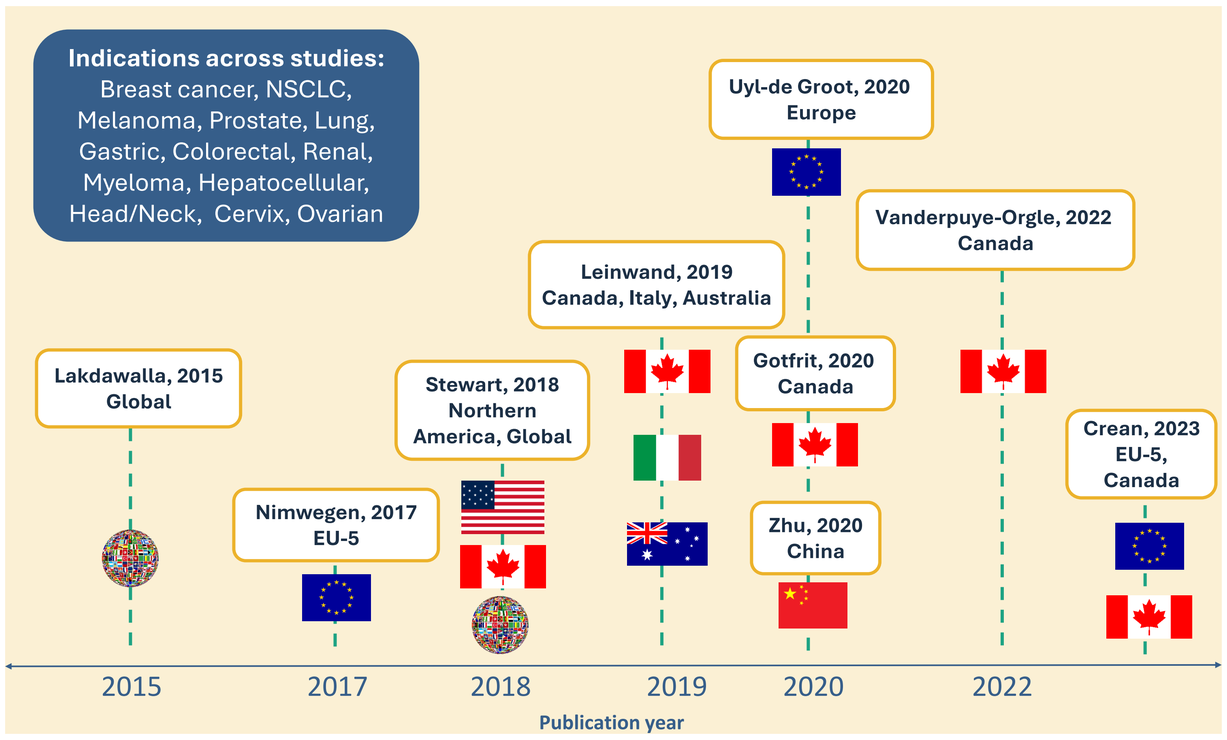
RESULTS

- A total of 247 studies were screened. Nine studies that met the inclusion criteria, reporting impact of delay in costs or health outcomes due to access to a new oncology treatment, were included. Studies that only reported qualitative outcomes like causes of delay, barriers to treatment initiation, impact of delay due treatment initiation etc. were excluded.
- The studies included were from multi-country (n=6), Canada (n=2) and China (n=1) perspective (**Fig. 3**). There were five descriptive or mixed-methods studies, and four were model-based analyses.
- The indications considered were mostly non-small-cell lung cancer (NSCLC) (n=7), breast cancer (n=6), melanoma (n=3) and colorectal cancer (n=3).
- The definition of delay and outcomes were reported differently across studies, with life years and QALY loss as the commonly used measures. It was found time to patient access was dependent on the duration and variety of the HTA process, which differed across countries. [5]
- In Europe, the average time to market was reported as 403 days, and marketing approval was about 242 days later than in the United States (US) [1]. In China, the median delay was 44.4 months, compared to approval date of US or European Union (EU) [6].

Every year of delay in drug approvals could cost the world nearly **80,000 median life-years per treatment**. Timely access to life-saving treatments means more than just hope for patients, it results in **real lives saved**, increase in **quality of life** and reduced overall costs!

- An EU-5 study projected that over 5-years, delayed market access and reimbursement decisions would lead to potential absolute losses of 4,443 LYs, 0.08 LY/ patient, 3,101 QALYs and 0.06 QALY/patient, with highest loss expected in Italy [7]. In Canada, delays in NSCLC therapies may have affected 6400 patients, amounting to a loss of 1740 person-years of life and 1122 QALYs (valued at CA$112 million) [8].
- Delayed access to drugs like ipilimumab and abiraterone potentially resulted in >30,000 LYs lost [1]. The societal value of life days lost per patient ranged from $32,148 for ipilimumab in Italy to $101,565 for crizotinib in Australia [9].
- There was no relation found in time between registration by Food and Drug Administration (FDA) or EMA, and clinical value of the drugs as defined by clinical outcomes (OS, Progression Free Survival (PFS), or TTP), or European Society Medical Oncology-Magnitude of Clinical Benefit Scale (ESMO-MCBS) [1].
- A study reported that for every year by which time to drug approval could have been shortened, there would have been a median number of LYs potentially saved of 79,920 worldwide per drug. And if there is a reduction in the time required to take a drug from discovery to approval to 5 years, the median number of LYs saved per treatment would have been 523,890 worldwide [10].

Figure 3: Studies included in the analysis



CONCLUSIONS

- There is substantial potential LYs, QALYs, and economic loss to patients and society due to delays in accessing treatment. These delays and inequalities in access for patients are caused by various factors including complex frameworks with numerous stages of assessment, slow regulatory processes and reimbursements, and individual assessments frameworks of European nations. Even though FDA, EMA have expedited programs for assessment of certain category of drugs, more efforts are required by HTA systems to recognize the hurdles involved in each stage of approval process and work towards reducing these inequalities.
- With the introduction of the Joint Clinical Assessment (JCA) in EU, there is high potential to accelerate patient access by reducing the delay between marketing authorization and clinical assessment as JCA process will be performed in parallel with EMA marketing authorization. A life saving treatment can only save lives when patients have access to it.

*Note: Deep dive into grey literature was done up-to September 2024 to add further value to the results, given limited literature on the topic and the potential significant impact on patients. Three additional studies, not in the abstract, were found and reported in the poster.

References

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