

FDA BsUFA Meeting Biosimilars in Oncology Care: Nurse Perspectives

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Cancer

Cancer in the US

- > 1.8 million new diagnoses in 2020
- > 16 million cancer survivors, many living with chronic cancer
- Treatment of cancer with biologic drugs is increasing - high effectiveness and less side effects
- Shifting sites and modes of cancer care delivery
- Changing workforce demographics to meet needs of people with cancer and survivors
- Increasing cost of care and out-of-pocket expenses for patients

Nurses in Cancer Care

Oncology nurses in the US

- 3.9 million registered nurses
- Most trusted profession 18 years in a row
- > 104,000 oncology nurses (NSBN Survey, 2019)
- > 42,000 certified in oncology specialties
- Estimated 5200 - 7000 Advanced Practice Providers (APPs) including Nurse Practitioners (NPs) and Physicians Assistants (PAs) (ASCO APP Survey, 2018)
- Nurse Practitioners (NPs) have independent prescribing authority in 23 states (AANP Update, 2020)
- NPs prescribe growth factors (e.g., pegfilgastrim) and hematopoietic agents (e.g., epoetin), and renew antineoplastic treatments including monoclonal antibodies (e.g., trastuzumab)

Roles in Cancer Care Delivery

Oncology nurses and nurse practitioners

- Educate patients regarding medications and side effects
- Administer antineoplastic treatment
- Assess, triage, refer and report adverse events
- Serve on cancer committees for accreditation, process development and quality improvement
- Participate on formulary committees regarding selection of medications
- Collaborate with pharmacists on prescribed drugs
- Consult with insurers for prior authorization
- Serve on national guidelines development panels
- Assess patients for financial concerns and refer to counseling and services

Growing Global Costs



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7437115/>

NCI: Risk Factors Related to Financial Toxicity

Risk Factors

- Type of cancer, severity, and treatment received can affect the risk of financial toxicity
- Age, race, income, and employment can affect risk of financial toxicity
- Type of health insurance or not having health insurance
- Cancer survivors usually report higher out-of-pocket spending than people who have not had cancer
- Some cancer survivors report spending more than 20% of their annual income on medical care

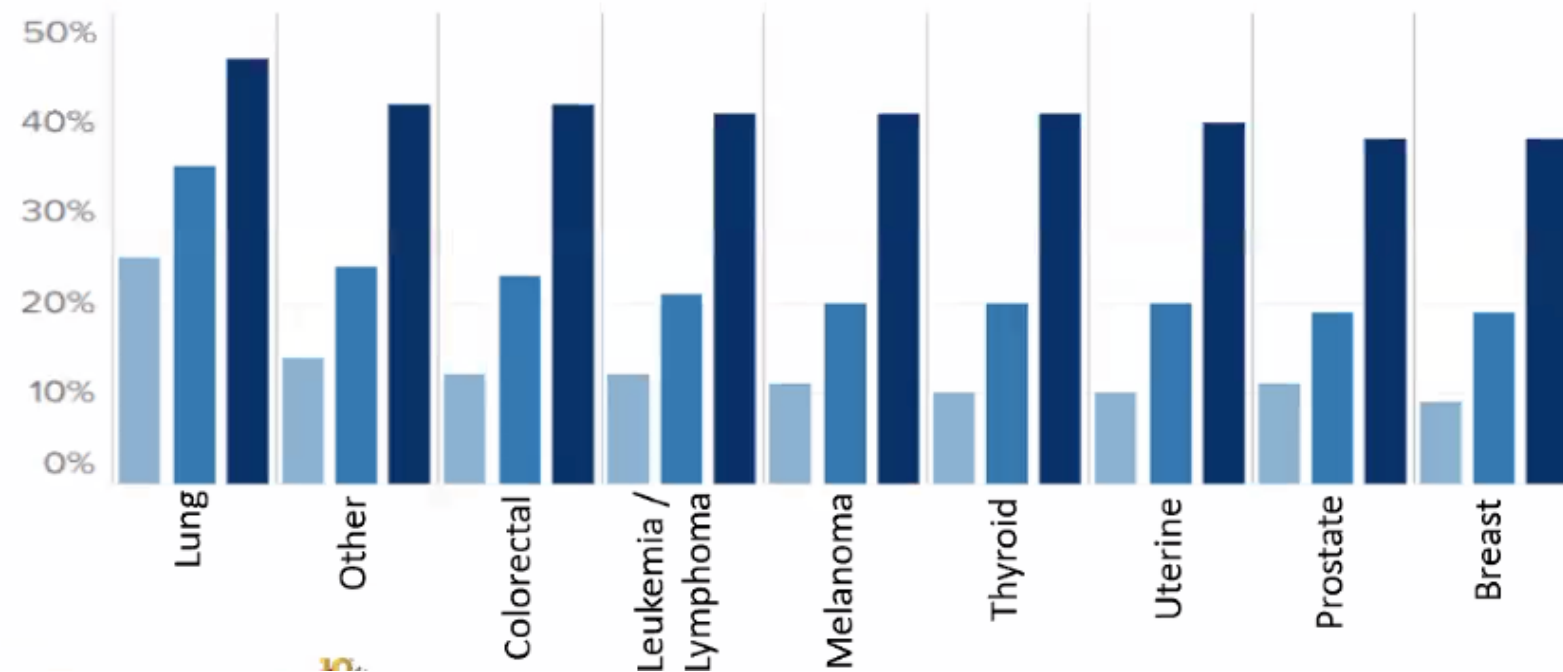
NCI: https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-pdq#_223

Cost of Cancer Care

Financial toxicity is a growing concern

Cumulative Probability of Bankruptcy for Surviving Patients in the First 5 Years After Diagnosis

Years After Diagnosis
■ 1 ■ 2 ■ 5



Primary causes of bankruptcy include high cost of treatments, filling insurance coverage gaps, and loss of income

Source: *Journal of Clinical Oncology*. Study included persons 21 and older at the time of diagnosis with cancers recorded in the Western Washington Cancer Surveillance System.

FDA Biosimilars Regulatory Policy

Biologics Price Competition and Innovation Act (BPCI Act) of 2009

- Abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-approved biological product
- Pathway to provide:
 - More treatment options
 - Increase access to lifesaving medications
 - Potentially lower health care costs through competition

FDA: <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>

Biosimilars in Oncology

Today, 28 FDA-approved biosimilars

Majority of biosimilars are in the oncology space

2015 - Zarxio (filgrastim-sndz)

2017 - Mvasi (bevacizumab-awwb)

- Ogivri (trastuzumab-dkst)

2018 - Retacrit (epoetin alfa-epbx)

- Fulphila (pegfilgrastim-jmdb)

- Nivestym (filgrastim-aafi)

- Udenyca (pegfilgrastim-cbqv)

- Truxima (rituximab-abbs)

- Herzuma (trastuzumab-pkrb)

2019 - Ontruzant (trastuzumab-dttb)

- Trazimera (trastuzumab-qyyp)

- Kanjinti (trastuzumab-anns)

- Zirabev (bevacizumab-bvzr)

- Ruxience (rituximab-pvvr)

- Ziextenzo (pegfilgrastim-bmez)

- Hylecta (trastuzumab +hyaluronidase-oysk)

2020 – Nyvepria (pegfilgrastim-apgf)

- Phesgo (pertuzumab, trastuzumab + hyaluronidase-zzxf)

Cancer Care Beyond 2020

Effective treatments, safe solutions, controlled costs

- Growing treatment options with testing and treatment for precision oncology
- > 16 million cancer survivors, many living with chronic cancer and ongoing costs
- Treatment of cancer with biologic drugs is increasing - high effectiveness and less side effects
- Expiring patents offer opportunities to lower costs with biosimilars
- Nurses and nurse practitioners are trusted partners in cancer care delivery and patient education
- Safe and effective care for people with cancer that patients can afford

