Patient Safety Secondary Cancers: What the Pharmacist Needs to Know

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Faculty Disclosures

- Dr. Holle is a consultant for McGraw Hill Education, Postgraduate Healthcare Education, Inc
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Learning Objectives

At the completion of this activity, the participant will be able to:

- Identify risk factors for developing secondary cancers
- Differentiate treatment options for secondary cancers from those of primary cancers at the same site
- Demonstrate pharmacist-driven interventions to reduce risk of, screen for, and optimally manage secondary cancers

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Secondary Cancers: What are They?

- Second primary cancer vs disease that has metastasized from the primary cancer
- Rare but becoming more frequent
  - Occurs in children and adults
  - Survivors are living longer
  - Better supportive care
  - More patients receiving treatment

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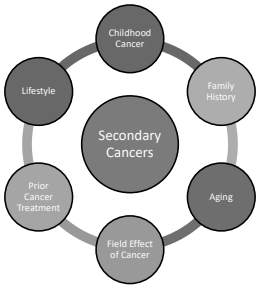
Rheingold SR, et al. Secondary Cancers in Kufe DW, et al, eds. Holland-Frei Cancer Medicine 6th edition; Hamilton (ON): BC Decker, 2003

5

Factors Which Can Lead to Secondary Cancers



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National Comprehensive Cancer Network. Available at: https://www.nccn.org/patients/resources/life_after_cancer/understanding.aspx. April 9, 2021.

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Most Common Types of Secondary Cancers

- Myeloid-related cancers
  - Acute myeloid leukemia
  - Myelodysplastic syndrome
  - Myelodysplastic syndrome/Myeloproliferative disorders
- Cutaneous malignancies
- Solid tumors
  - Breast cancer
  - Bone cancers and sarcomas
  - Gastrointestinal cancers
  - Squamous cell carcinoma of skin/oral cavity
  - Thyroid cancer

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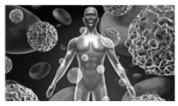
Therapy-Related Myeloid Cancers

- Incidence: 5-20%
- Highest incidence
  - Hodgkin lymphoma
  - Non-Hodgkin lymphoma
  - Breast cancer
  - Gynecologic cancers
- Diseases progresses quickly; more resistant to conventional therapy; inferior outcomes



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National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed April 12, 2021.

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Therapy-Related Myeloid Cancers

- Exposure to DNA-damaging agents
  - Cytotoxic chemotherapy
    - Alkylating agents
    - Topoisomerase II inhibitors
    - Other agents (chemotherapy/colony-stimulating growth factors)?
    - Poly (ADP-ribose) polymerase (PARP) inhibitors
  - Radiation therapy
- Additional factors
  - Age
  - Inherited predisposition

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Swerdlow SH, et al, eds. World Health Organization classification of tumours of haemoatopoietic and lymphoid tissues. 2017; Churpek JE, et al. *Best Pract Res Clin Haematol*. 2013;26:309; Churpek JE, et al. *Cancer*. 2016;122:304.

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DNA-Damaging Agents

Alkylating Agents	Topoisomerase II Inhibitors	PARP Inhibitors	Other Agents
Busulfan	Daunorubicin	Niraparib	Docetaxel
Carboplatin	Doxorubicin	Olaparib	Fludarabine
Carmustine	Etoposide	Rucaparib	Methotrexate
Chlorambucil	Mitoxantrone	Talazoparib	Paclitaxel
Cisplatin	Teniposide		Vincristine
Cyclophosphamide			Vinblastine
Dacarbazine			
Lomustine			
Melphalan			*Filgrastim*
Mitomycin			*Pegfilgrastim*
Procarbazine			
Thiotepa			

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Swerdlow SH, et al, eds. World Health Organization classification of tumours of haemoatopoietic and lymphoid tissues. 2017.

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Therapy-Related Myeloid Cancers

- Incidence varies with treatment exposure and underlying disease
  - Median diagnosis age: 61 yr
  - Prior malignancy: 80%
  - Hodgkin lymphoma > breast cancer
  - First 5 yr after treatment: highest risk
- Type of prior malignancy
  - Solid tumor: 70%
  - Hematologic malignancy: 30%

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Granfeldt Ostgard LS, et al. *J Clin Oncol*. 2015;33:3641; Morton LM, et al. *Blood*. 2013;121:2996; Morton LM, et al. *JAMA Oncol*. 2019;5:318

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AML Treatment

Induction

- 7+3: cytarabine 100-200 mg/m^2 CIVI daily day 1-7 + anthracycline (either idarubicin 12 mg/m^2/d OR daunorubicin 60 mg/m^2/d IV) day 1-3

Consolidation

- High-dose cytarabine x 3-4 cycles
- Matched sibling hematopoietic stem cell transplantation (HSCT)

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National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed April 12, 2021.

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Therapy-Induced AML Treatment

Induction

- Dual liposomal encapsulation of cytarabine (100 mg/m^2) and daunorubicin (44 mg/m^2) days 1, 3, and 5 x 1 cycle; 2nd induction days 1 and 3 only
- 7+3

Consolidation

- Dual liposomal encapsulation of cytarabine (65 mg/m^2) and daunorubicin (29 mg/m^2) days 1 and 3 x 1-2 cycles
- Matched-sibling HSCT
- High-dose cytarabine

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National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2021 Acute myeloid leukemia. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed April 12, 2021.

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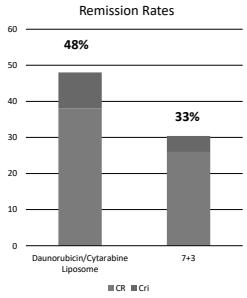
Daunorubicin/Cytarabine Liposome



1 yr Survival

- **Daunorubicin/ cytarabine liposome: 42%**
- 7+3 28%

5-yr Survival

- **Daunorubicin/ Cytarabine Liposome: 18%**
- 7+3: 8%

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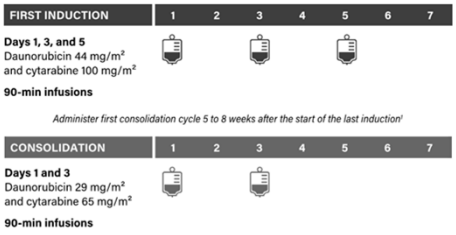
Daunorubicin/Cytarabine Liposome



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Daunorubicin/Cytarabine Liposome (Vyxeos®)

At-a-Glance Drug Information	
FDA Approval	Adults with newly diagnosed therapy-related AML or MDS
Dosing changes	Toxicity, hepatic and renal dysfunction
Metabolism	Same as convention but longer half-life (30-40 hr)
DDIs	No significant; cardiotoxic, hepatotoxic
Warnings	• BBW: Do NOT interchange with other daunorubicin or cytarabine-containing products • Hemorrhage • Cardiotoxicity • Hypersensitivity • Copper overload • Tissue necrosis • Embryo-fetal toxicity
Toxicities	Hemorrhagic events, febrile neutropenia, rash, edema, nausea, mucositis, diarrhea, constipation, musculoskeletal pain

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BBW; black box warning; DDI, drug-drug interaction. Vyxeos [package insert]. Jazz Pharmaceuticals; Palo Alto, CA, 2021.

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PARP Inhibitors and Myeloid Diseases

- Poly ADP ribose polymerase (PARP) plays important role in DNA repair pathways
- PARP inhibitors
  - Niraparib
  - Olaparib
  - Rucaparib
  - Talazoparib

- Used in breast, ovarian, pancreatic, and prostate cancers

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Morice P-M, et al. *Lancet Haematol.* 2021;8:3122-34.

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PARP Inhibitors and Myeloid Diseases

- Few case reports
- Carry warnings of MDS/AML
  - Incidence 0.3-1.7%
  - Duration of therapy 0.1 mo – 4.9 yr
  - Most also had previous platinum or other DNA-damaging agents
  - Prostate cancer trials report no incidence
- Meta-analysis 2021
  - Significant increased risk, odds ratio 2.63; *P*=0.026
  - Incidence: 0.73% (95% CI, 0.5-1.07)
  - Median treatment duration: 9.8 mo (IQR: 3.6-17 mo)
  - Latency period: 17.8 mo (range, 8.4-29 mo)

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Niraparib [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2020; Olaparib [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals, Inc.; March 2021; Rucaparib [package insert]. Boulder, CO: Clovis Oncology, Inc; October 2020; Talazoparib [package insert]. New York, NY: Pfizer Labs; October 2020; .

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PARP Inhibitors and Myeloid Diseases

- Remain vigilant during and after therapy
- Monitor CBC+ diff baseline & monthly; weekly if toxicity occurs
- Do not start medication until adequate recovery from hematologic toxicity
- Refer to hematologist if no recovery in 4 wk

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Niraparib [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2020; Olaparib [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals, Inc.; March 2021; Rucaparib [package insert]. Boulder, CO: Clovis Oncology, Inc; October 2020; Talazoparib [package insert]. New York, NY: Pfizer Labs; October 2020.

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Pause and Ponder

How does secondary AML from PARP inhibitors differ than that from cytotoxic chemotherapy?

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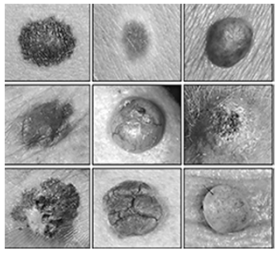
Secondary Cutaneous Malignancies



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Secondary Cutaneous Malignancies

- Basal cell carcinoma
- Keratoacanthoma
- Squamoproliferative lesions
- Squamous cell carcinoma
- Second primary melanoma

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Anticancer Therapy Associated with Cutaneous Malignancies

Anticancer Therapy	Drugs Within Class	Approved Indications	Cutaneous Malignancy
BRAF inhibitors	Dabrafenib, vemurafenib	Melanoma, NSCLC, papillary thyroid cancer, colorectal cancer, renal cell carcinoma	Keratoacanthoma; squamoproliferative lesion; squamous cell carcinoma
Multikinase inhibitors	Sorafenib, sunitinib	Hepatocellular carcinoma, renal cell carcinoma	Basal cell carcinoma; keratoacanthoma; squamoproliferative lesion; squamous cell carcinoma
	Ripretinib	Gastrointestinal sarcomas	Keratoacanthoma; squamous cell carcinoma
Janus kinase inhibitors	Ruxolitinib	Myelofibrosis, polycythemia vera	Squamous cell carcinoma
PD-1 inhibitors	Cemiplimab, nivolumab, pembrolizumab	Melanoma, NSCLC, head and neck, squamous cell carcinoma, many many others	Basal cell carcinoma; keratoacanthoma; squamous cell carcinoma
XRT	NA	Solid tumors	Basal cell carcinoma
Sonic hedgehog inhibitors	Vismodegib	Basal cell carcinoma; basal cell nevus syndrome	Squamous cell carcinoma

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BRAF, b-type rapidly accelerated fibrosarcoma kinase; NA, not applicable; NSCLC, non-small cell lung cancer; PD-1, programmed cell death 1; XRT, radiation therapy. Deutsch A, et al. *J Am Acad Dermatol.* 2020;83:1425-33.

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BRAF Inhibitors & Squamoproliferative Lesions

- 31% of patients develop premalignant and malignant lesions
- Accelerated transition within weeks to months of therapy initiation
- Factors associated with increased risk of SCC
  - Older age
  - Recent treatment initiation
  - Previous sun damage
  - Vemurafenib > dabrafenib
- Combination therapy with MEK inhibitor decreases risk
- Close monitoring during and after therapy

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BRAF, b-type rapidly accelerated fibrosarcoma kinase; MEK, mitogen activated protein kinase; SCC, squamous cell carcinoma. Deutsch A, et al. *J Am Acad Dermatol.* 2020;83:1425-33.

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BRAF Inhibitors & Second Cutaneous Melanoma

- Less common
- Develops weeks to months after BRAF therapy initiation
- Pathogenesis unknown
- Close monitoring during and after therapy

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BRAF, b-type rapidly accelerated fibrosarcoma kinase. Deutsch A, et al. *J Am Acad Dermatol.* 2020;83:1425-33.

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Multikinase Inhibitors and Cutaneous Malignancies

- More frequent with sorafenib (13.5%) vs sunitinib (6.3%) vs Ripretinib (4.7%)
- Risk factors not clearly established
- Manifest on sun-exposed areas and in those with other cutaneous events
- Timeframe: months after initiation
- Treatment
  - Maintain treatment for underlying malignancy
  - Surgically remove if possible
  - Temporary hold until resolution

UCONN SCHOOL OF PHARMACY

Deutsch A, et al. *J Am Acad Dermatol.* 2020;83:1425-33; Ripretinib [package insert]. Waltham, MA; Deciphera Pharmaceuticals, LLC. May 2020.

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Vismodegib and Cutaneous Malignancies

- Sonic hedgehog inhibitor used in treatment of locally advanced or metastatic BCC or basal cell nevus syndrome
- Typically no history of SCC
- Timeline: weeks to months after initiation
- Pathogenesis hypotheses
  - Selection of SCC cells already present
  - Activation RAS/MAPK pathway
- Close dermatologic monitoring recommended

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Deutsch A, et al. *J Am Acad Dermatol.* 2020;83:1425-33.

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Ruxolitinib and PD1 Inhibitors and Cutaneous Malignancies

- Ruxolitinib used
  - Hematologic and rheumatologic disorders
  - Dermatologic conditions
  - Graft vs host disease
- Evolving data on incidence and progression
- Full body skin examinations recommended
- Checkpoint inhibitors used in a variety of solid tumors
- Case reports (n=5) of basal cell carcinoma, squamous cell carcinoma, keratoacanthoma
- Continued reporting is recommended

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Deutsch A, et al. *J Am Acad Dermatol.* 2020;83:1425-33.

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Tamoxifen and Endometrial/Uterine Cancer

- Women $\geq$ 50 yr: increased risk of endometrial cancer (RR, 4.01; 95% CI, 1.70-10.90)
- Updated results of NSABP studies
  - Increased endometrial cancer
  - Increased uterine sarcomas
- FDA issued "black box" warning
- Raloxifene: not associated with risk

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CI, confidence interval; RR, relative risk. Fisher B, et al. *J Natl Cancer Inst.* 1998;90:1371-1388; Fisher B, et al. *J Natl Cancer Inst.* 2005;97:1652-1662; NCCN Guidelines Version 1.2021 Breast Cancer Risk Reduction. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast_risk.pdf Accessed April 13, 2021.

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Tamoxifen and Endometrial/Uterine Cancer

- Women with intact uterus
  - Baseline gynecologic assessment
  - Follow-up gynecologic exams at each visit
  - Prompt evaluation of vaginal bleeding
- No routine role of endometrial ultrasound/biopsy
- Discontinue treatment if cancer occurs; at least until fully treated

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CI, confidence interval; RR, relative risk. NCCN Guidelines Version 1.2021 Breast Cancer Risk Reduction. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast_risk.pdf Accessed April 13, 2021.

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Radiation Therapy and Secondary Malignancies

- 5% incidence
- Risk factors
  - Age at exposure
  - Gender
  - Temporal association
  - Radiation technique
  - Radiation type
- Often occurs at within the field of radiation

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Dracham CB, et al. *Radiat Oncol J.* 2018;36:85-94.

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Radiation Therapy and Cutaneous Malignancies

- Develop 2 years after radiation therapy
- Basal cell carcinoma most common
- Risk factors
  - Higher total irradiation dose
  - Modality of radiation (2-dimensional conformal > intensity-modulated > 3-dimensional > proton therapy)
  - Increased elapsed time from radiotherapy
  - Increased ultraviolet susceptibility/lighter skin type
  - Younger age at time of radiation therapy
  - Genetic predisposition
  - Lifestyle aspects
  - Exposure to other carcinogens
- More aggressive, harder to eradicate, more prone to recurrence
- Close, lifelong dermatologic evaluation

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Deutsch A, et al. *J Am Acad Dermatol.* 2020;83:1425-33.

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Radiation Therapy and Sarcoma

- 3-6% of all sarcomas
- Mean age of diagnosis
  - Adults: 50-67 yr
  - Children: 16-33 yr
- Common primary cancers in adults
  - Breast cancer
  - Gynecologic cancers
  - Head and neck cancers
  - Lymphomas
- Common primary cancers in children
  - Ewing's sarcoma
  - Hodgkin lymphoma
  - Rhabdomyosarcoma
  - Retinoblastoma

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Maki R, et al. Radiation-associated sarcoma. UptoDate. 2021.

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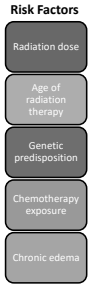
Radiation Therapy and Sarcoma



- Prognosis:
  - 5-yr survival: 10-50%
- Treatment
  - Similar to primary sarcomas

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Maki R, et al. Radiation-associated sarcoma. UptoDate. 2021.

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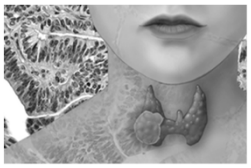
Radiation Therapy and Thyroid Cancer

- Radiation exposure during childhood increase risk of
  - Thyroid cancer
  - Benign thyroid nodules
  - Hypothyroidism
- Exposure from
  - Diagnostic radiographs
  - Therapeutic radiation
  - Internal exposure



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Scheider AB, et al. Radiation-induced thyroid cancer. UptoDate. 2021.

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Radiation Therapy and Thyroid Cancer

- Surveillance recommended for children with history of
  - radiation exposure to neck
  - environmental exposure
- Includes
  - Annual history
  - Annual physical examination
  - Assessment of thyroid function tests
- Medical exposure
  - Minimize
  - Consider risks/benefits
- Nuclear accident
  - Potassium iodide tablets

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Scheider AB, et al. Radiation-induced thyroid cancer. UptoDate. 2021.

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Survivors and Secondary Cancers

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Hodgkin Lymphoma and Secondary Cancers

- Radiation dose and fields
- Chemotherapy agents and doses administered
- Patient age at treatment
- Length of time after treatment
- Family history
- Smoking history
- Genetic predisposition

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Bonnadonna G, et al. *N Engl J Med*. 1973;288:1242; Cannelllos GP, et al. *Lancet*. 1975;1:947; Arsenauau JC, et al. *N Engl J Med*. 1972;287:1119; Schaapveld M, et al. *N Engl J Med*. 2015;373:2499.

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Hodgkin Lymphoma and Secondary Cancers

- Solid tumors most common
  - Breast
  - Lung
  - Gastrointestinal cancers
- Relative risk compared with general population
  - Leukemia: 10-80 fold relative risk
  - Non-Hodgkin lymphoma: 3-35 fold relative risk
  - Solid tumors: > 2-fold relative risk
- Prognosis: worse than primary cancers

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LaCasce AS, et al. Second malignancies after treatment of classic Hodgkin lymphoma. UptoDate. 2021

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Hodgkin Lymphoma and Secondary Cancers

Overall	• Treatment summary provided to primary care provider • Patient education • History and physical exam annually after 5 yr
Thyroid Cancer	• Thyroid stimulating hormone (TSH) annually if XRT to neck
Leukemia	• Complete blood count annually
Solid tumors	• Breast cancer screening annually (starting 8-10 yr post therapy or age 40, whichever first) • Other routine cancer screening per guidelines (cervical, colorectal, endometrial, lung and prostate) • Self breast and skin exams

UCONN SCHOOL OF PHARMACY

NCCN Guidelines Version 3.2021 Hodgkin lymphoma. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf. Accessed April 12, 2021.

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Testicular Cancer and Secondary Cancers

- Solid tumors
  - 2-fold increased risk
  - Lung, colon, bladder, pancreas, stomach
  - Median latency: 12.5 yr
- Skin cancers
- Hematologic malignancies
- Contralateral testicular cancer: 1-3%

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Gilligan T, et al. *Urol Oncol*. 2015;33:413; Motzer RJ, et al. J *Natl Compr Canc Netw*. 2012;10:502; Bosl GJ, et al. *N Engl J Med*. 1997;337:242, Ritchie JP, et al. *Urology*. 2011;78:S425.

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Pause and Ponder

What can you do as a pharmacist to help survivors of cancer who are at risk of secondary cancers?

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Pharmacist's Role

- Patient education
  - Importance of close follow-up long term
  - Self screening
  - Healthy lifestyle habits
- Advocate for screening and early detection
- Monitor for long-term toxicities
  - Refer patients with signs and symptoms to physician
  - Participate in screening/early detection programs
- Recommend appropriate treatment for secondary cancers

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Survivorship Guidelines

- National Comprehensive Cancer Network Survivorship Guidelines and Adolescent and Young Adult Oncology https://www.nccn.org/professionals/physician_gls/pdf/survivorship.pdf

  https://www.nccn.org/professionals/physician_gls/pdf/aya.pdf

- Children's Oncology Group Long-Term Follow-up Guidelines http://www.survivorshipguidelines.org/

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Example Screening Guidance

Treatment	Increased Cancer Risk	Screening and Early Detection Recommendations	Other
Chest XRT	Breast	Breast MRI and mammogram annually at 30 yr or 8 yr after XRT	Consider chemoprevention based on risk
	Skin cancer	Annual skin exam and/or dermatology referral	Counsel sun safety and regular sunscreen SPF ≥ 30
	Sarcoma	Image as indicated	
	Lung cancer	Image as indicated	Counsel tobacco cessation; lung cancer screening based on risk
Tamoxifen	Uterine cancer	Assess vaginal pain or bleeding annually; if bleeding refer to gynecology for transvaginal ultrasound and biopsy	Increased in postmenopausal women

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NCCN Guidelines Version 1.2021 Survivorship. Available at: https://www.nccn.org/professionals/physician_gls/pdf/survivorship.pdf. Accessed April 12, 2021.

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Healthy Lifestyle Recommendations

- Achieve and maintain healthy bodyweight throughout life
- Engage in physical activity daily
- Minimize alcohol intake
- Avoid/stop using tobacco products
- Practice sun safety
- Ensure adequate amount of sleep
- Follow-up with primary care provider regularly
- Obtain nutrients from food sources

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NCCN Guidelines Version 1.2021 Survivorship. Available at: https://www.nccn.org/professionals/physician_gls/pdf/survivorship.pdf. Accessed April 12, 202

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Summary

- Although secondary cancers are rare, understanding risk and having a high suspicion can facilitate early diagnosis and better outcomes
- Both general risk factors as well as treatment or disease-specific risk factors for developing secondary cancers exist
- General secondary cancers are treated similarly to primary cancers at same origin
- Except to treatment is secondary AML/MDS which benefits from daunorubicin/cytarabine liposome
- Pharmacists can play an important role in education and facilitating survivors of cancer to engage in risk reduction and screening practices
- Pharmacists should remain up-to-date and vigilant with caring for survivors of cancer

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Questions?

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