



SARAH CANNON

Blood Cancer Network

BLOOD AND MARROW TRANSPLANT : AUTOLOGOUS TRANSPLANTS & TELEMEDICINE

Saturday, April 13, 2019

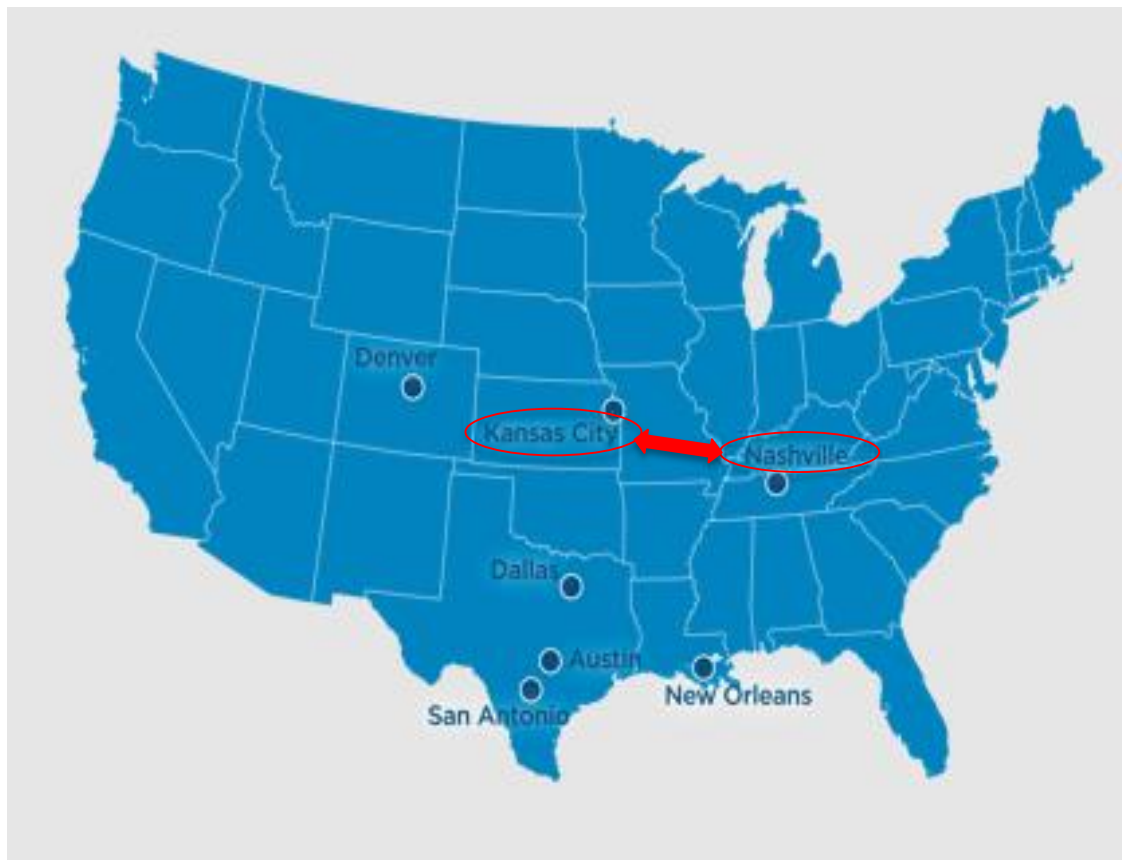
Jenna Bell, MJ, RN, OCN – *Administrative Director, Sarah Cannon BMT Program at Research Medical Center*

OBJECTIVES

1. Introduction to the Sarah Cannon BMT Program at Research Medical Center and our providers.
2. Review of indications for autologous transplant, recommended referral timing, and outcomes.
3. Review of post-transplant care recommendations.
4. Review of telemedicine and its capabilities and uses at Sarah Cannon Blood Cancer Center and BMT Program.

SARAH CANNON BMT PROGRAM

- Joint BMT Program between Research Medical Center (RMC) in Kansas City and TriStar Centennial Medical Center (TCMC) in Nashville
- FACT Accreditation through TCMC
- Cell collection and transplantation at RMC
- Cell storage at TCMC



OUR PROVIDERS

- Sarah Cannon BMT Program Director for the Nashville and Kansas City sites
- Sarah Cannon BMT Director of Research
- Foundation for the Accreditation of Cellular Therapy (FACT) inspector and board member
- Board-certified in hematology and oncology



Carlos Bachier, MD

OUR PROVIDERS



Suman Kambhampati, MD

- Sarah Cannon BMT Clinical Program Director
- Sarah Cannon Blood Cancer Co-Medical Director
- Clinical interest include:
 - Blood and marrow transplant
 - Multiple myeloma
 - Acute leukemia
 - Chronic lymphocytic leukemia
 - Leukemia in the elderly population
 - Myelodysplastic syndrome
- Board-certified in internal medicine with a subspecialty in hematology/oncology

OUR PROVIDERS

- Sarah Cannon Blood Cancer Program
Co-Medical Director
- Clinical interest include:
 - Blood and marrow transplant
 - Blood cancers
 - Blood disorders
 - Acute leukemia
- Board-certified in hematology and oncology



Frank Slovick, MD

OUR PROVIDERS

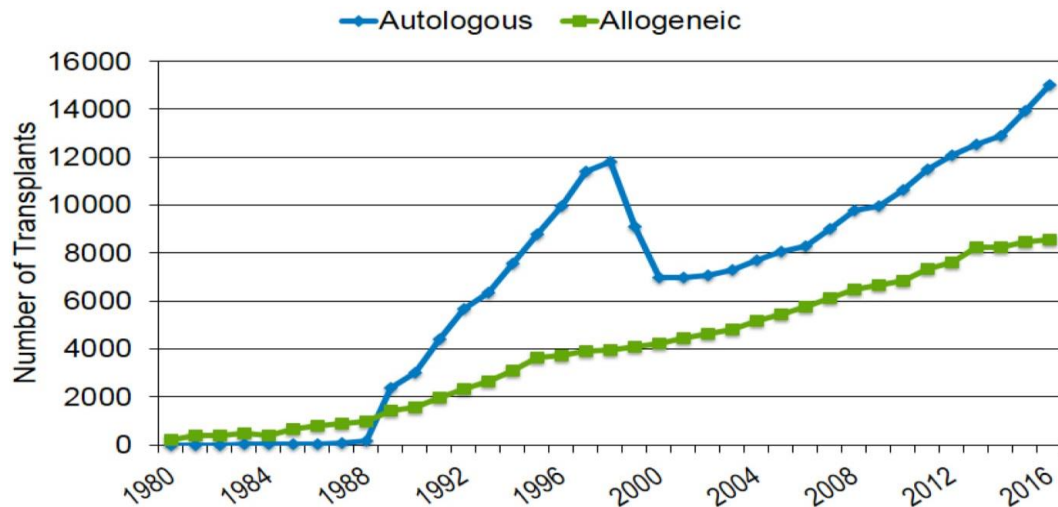


*Julie Wilhauk, DNP,
APRN, AOCNP*

- Board-certified as an advanced practice oncology nurse practitioner
- Clinical interest include:
 - Blood and marrow transplant
 - Blood cancers
- Provides comprehensive health management including performing bone marrow biopsies and management of patient needs

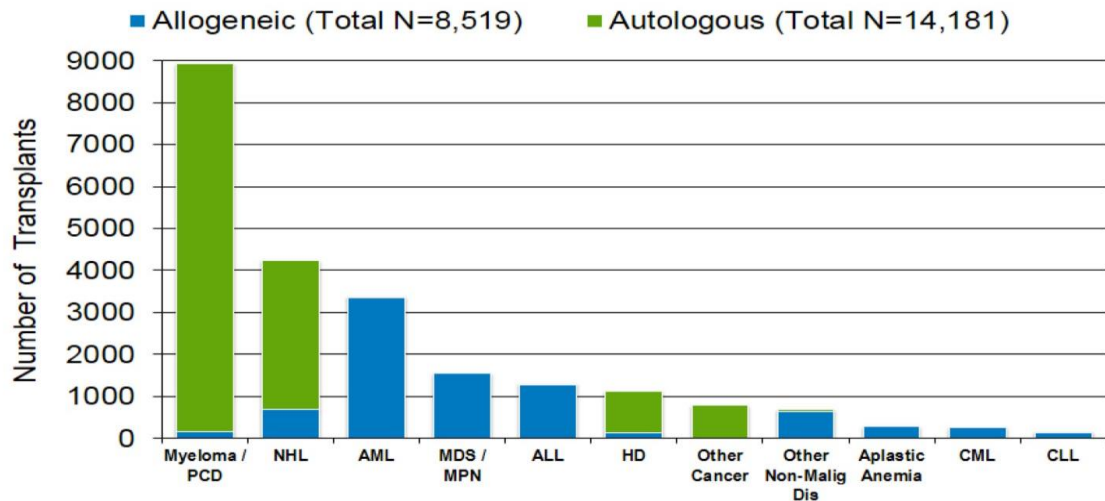
CIBMTR TRANSPLANT DATA – CURRENT STATE IN THE U.S.¹

Annual Number of HCT Recipients in the US by Transplant Type



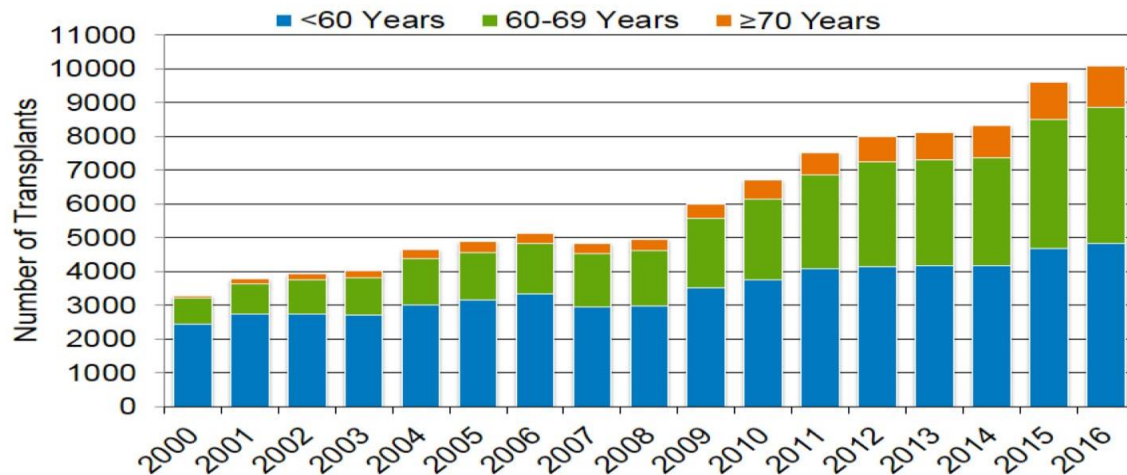
CIBMTR TRANSPLANT DATA – CURRENT STATE IN THE U.S.¹

Indications for Hematopoietic Cell Transplant in the US, 2016



CIBMTR TRANSPLANT DATA – CURRENT STATE IN THE U.S.¹

Trends in Autologous HCT in the US by Recipient Age[^]

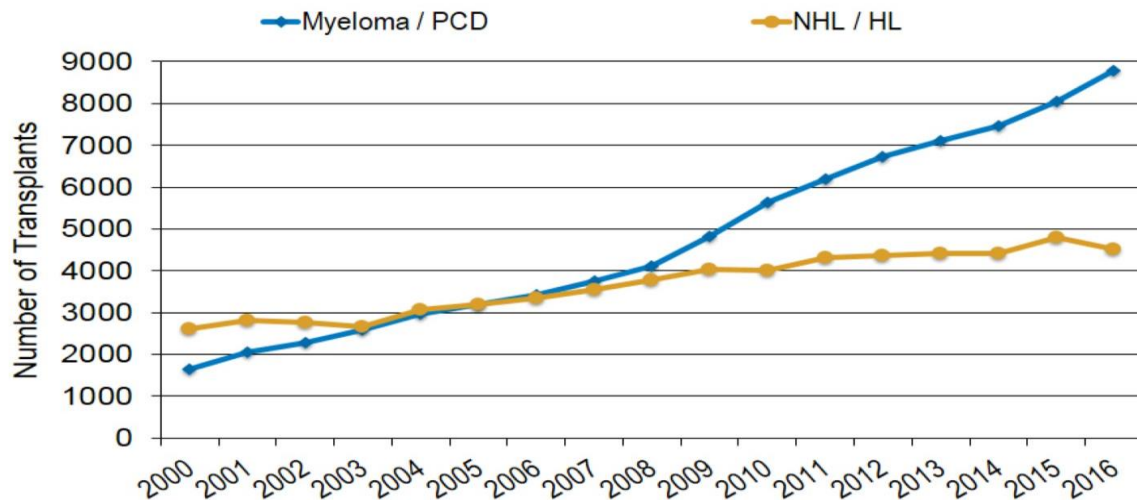


[^]Transplants for NHL, Hodgkin Disease and Multiple Myeloma

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CIBMTR TRANSPLANT DATA – CURRENT STATE IN THE U.S.¹

Selected Disease Trends for Autologous HCT in the US

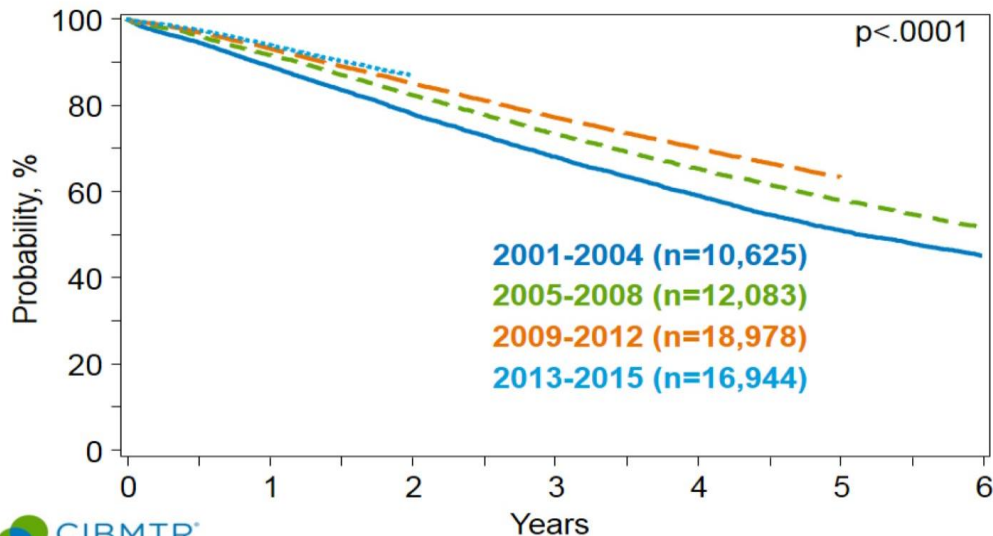


BMT REFERRAL TIMING – *MULTIPLE MYELOMA*¹

When to refer for transplant evaluation:

- At diagnosis
- At first progression

Trends in survival after Autologous HCT for Multiple Myeloma, 2001-2015

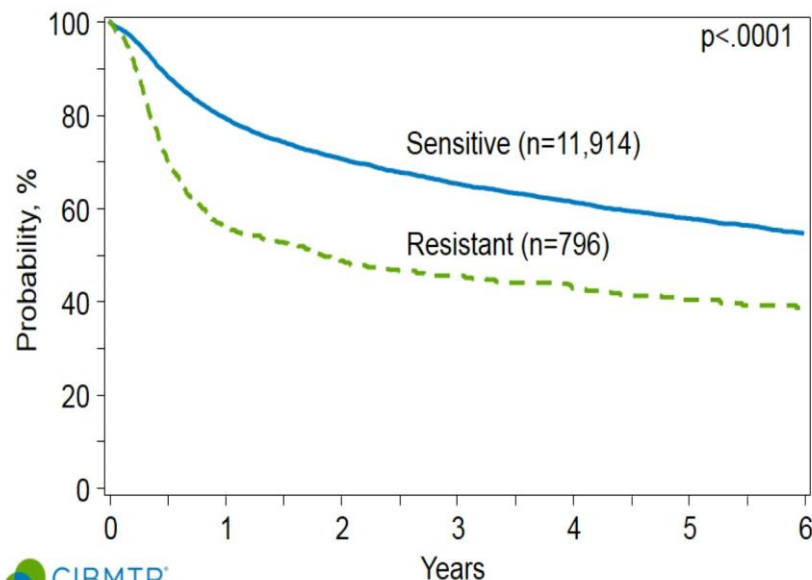


BMT REFERRAL TIMING – DLBCL¹

When to refer for transplant evaluation:

- Primary induction failure, including PET avid disease
- First relapse
- CR2 or subsequent remission
- Double or triple hit at diagnosis (*MYC* and *BCL-2* and/or *BCL-6*)
- Primary CNS lymphoma at diagnosis

Survival after Autologous HCT for Diffuse Large B-cell Lymphoma (DLBCL), 2005-2015

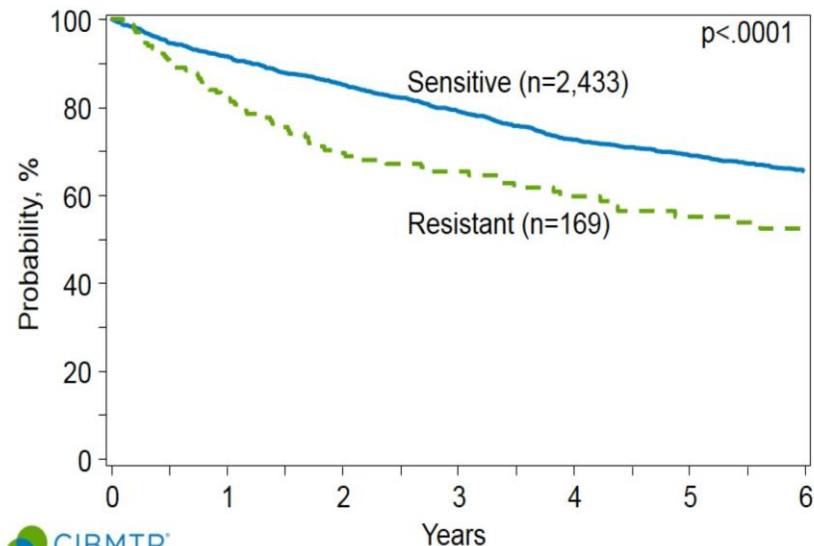


BMT REFERRAL TIMING – FOLLICULAR LYMPHOMA¹

When to refer for transplant evaluation:

- Poor response to initial treatment
- Initial remission duration < 24 months
- First relapse
- Transformation to DLBCL

Survival after Autologous HCT for Follicular Lymphoma, 2005-2015

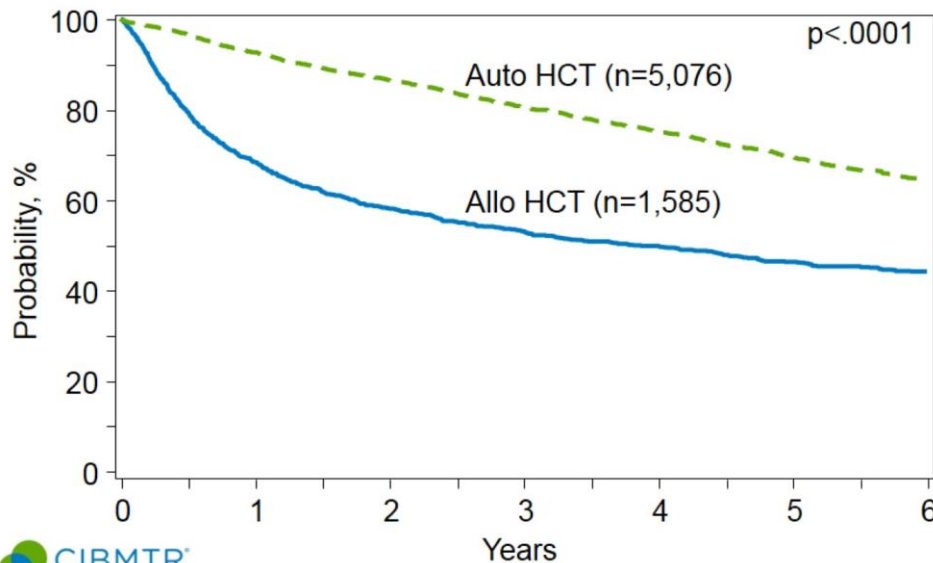


BMT REFERRAL TIMING – *MANTLE CELL LYMPHOMA*¹

When to refer for transplant evaluation:

- At diagnosis
- First relapse
- Bruton's tyrosine kinase (BTK) intolerant or resistant disease

Survival after Allogeneic or Autologous HCT for Mantle Cell Lymphoma, 2005-2015



BMT REFERRAL TIMING – *HIGH GRADE LYMPHOMAS*¹

When to refer for transplant evaluation:

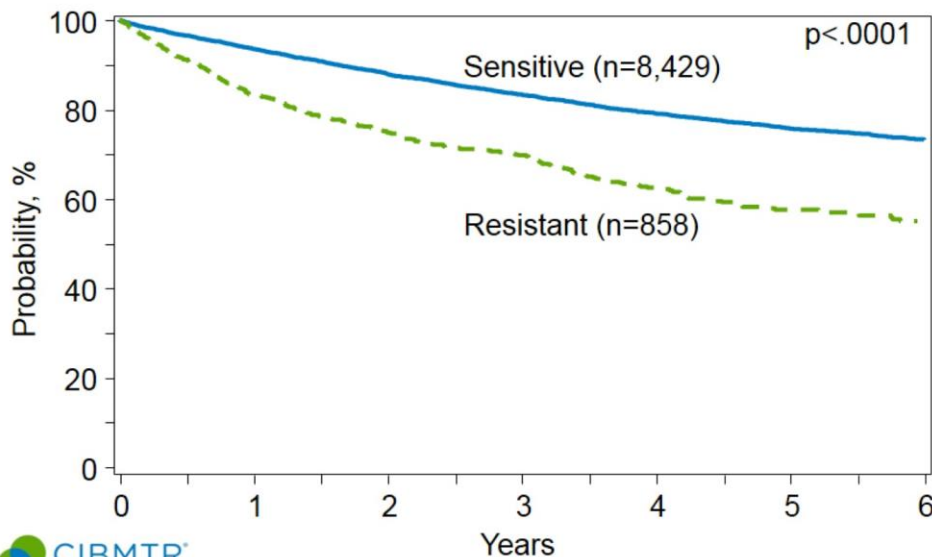
- C-myc rearrangement at diagnosis
- Primary induction failure
- CR1
- First relapse
- CR2 or subsequent remission

BMT REFERRAL TIMING – *HODGKIN LYMPHOMA*¹

When to refer for transplant evaluation:

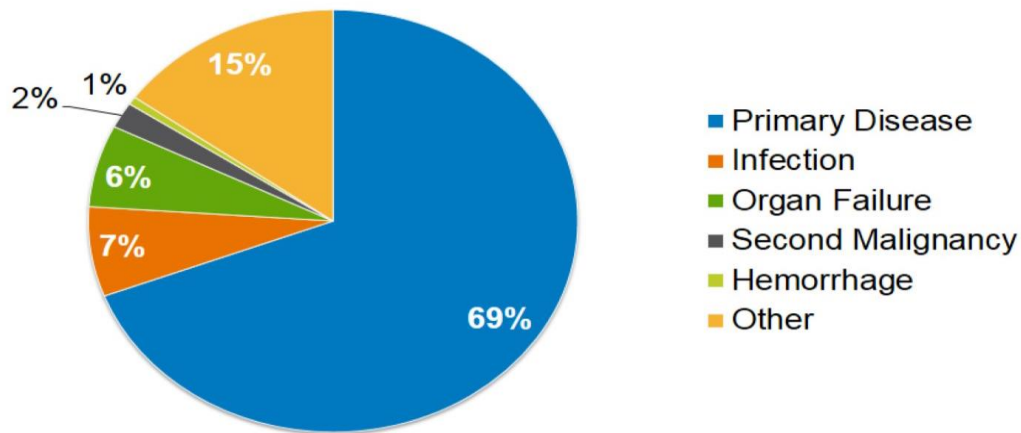
- Primary induction failure
- First relapse
- CR2 or subsequent remission

Survival after Autologous HCT for Hodgkin Lymphoma, 2005-2015



CIBMTR TRANSPLANT DATA – CAUSES OF DEATHS¹

Causes of Death after Autologous HCT done in 2014-2015



POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Immune system	Complications: <ul style="list-style-type: none"> Infections Tests: <ul style="list-style-type: none"> CMV antigen or PCR testing in patients at high risk for CMV reactivation Radiologic studies (e.g., chest X-ray, CT scan) Immunoglobulin levels, T-cell subset tests 	All HCT recipients			
		Pneumocystis pneumonia (PCP) prophylaxis for initial 6 months after HCT	✓		
		Immunizations post-transplant according to published guidelines (see Part II: Vaccinations)	✓	✓	✓
		Administration of antibiotics for endocarditis prophylaxis according to American Heart Association guidelines Visit http://circ.ahajournals.org/content/116/15/1736.full.pdf	✓	✓	✓
		Additional measures for special populations*			
		Antimicrobial prophylaxis targeting encapsulated organisms for the duration of immunosuppressive therapy	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids
		Antimicrobial prophylaxis targeting PCP for the duration of immunosuppressive therapy	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids
		Screening for CMV in patients at high risk for CMV reactivation	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids

Key:

✓ = recommended preventative measures

* = Assessment recommended for patients with pre-existing conditions, if clinically indicated, if abnormal testing in a previous time period, or with new signs/symptoms

*Special populations = GVHD (patients with GVHD), Steroids (patients with ongoing significant corticosteroid exposure), Pediatric (pediatric patients), TBI (patients who have received total body irradiation)

POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Ocular	Complications: <ul style="list-style-type: none"> • Cataracts • Microvascular retinopathy • Sicca syndrome Tests: <ul style="list-style-type: none"> • Ophthalmologic exam 	All HCT recipients			
		Routine ocular clinical symptom evaluation; prompt ophthalmologic examination in patients with visual symptoms	✓	✓	✓
		Ophthalmologic examination with measurement of visual acuity and fundus examination		✓	+
		Additional measures for special populations*			
		Routine clinical evaluation, and if indicated, ophthalmologic examination more frequently	✓ GVHD	✓ GVHD	✓ GVHD
Oral	Complications: <ul style="list-style-type: none"> • Sicca syndrome • Caries • Periodontal disease • Oral cancer Tests: <ul style="list-style-type: none"> • Dental assessment 	All HCT recipients			
		Clinical oral assessment with particular attention to intra-oral malignancy evaluation	✓	✓	✓
		Check for history of xerostomia and high-risk habits and provide education about preventive oral health practices	✓	✓	✓
		Dental assessment. Perform a thorough oral, head and neck and dental exam		✓	✓
		Additional measures for special populations*			
		Assessment of teeth development		✓ Pediatric	✓ Pediatric
		Consider more frequent oral and dental assessments with particular attention to intra-oral malignancy evaluation	✓ GVHD	✓ GVHD	✓ GVHD

POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Respiratory	Complications: <ul style="list-style-type: none"> • Idiopathic pneumonia syndrome • Bronchiolitis obliterans syndrome • Cryptogenic organizing pneumonia • Sino-pulmonary infections Tests: <ul style="list-style-type: none"> • Pulmonary function testing (PFT) • Radiologic studies (e.g., chest X-ray, CT scan) 	All HCT recipients			
		Routine clinical pulmonary evaluation	✓	✓	✓
		Assessment of tobacco use and counseling against smoking	✓	✓	✓
		PFT and focused radiologic assessment as clinically indicated for patients with symptoms or signs of lung compromise	✓	✓	✓
		Additional measures for special populations*			
		Some experts recommend earlier and more frequent clinical evaluation and PFTs	✓ GVHD	✓ GVHD	✓ GVHD

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POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Cardiac and vascular	Complications: <ul style="list-style-type: none"> • Cardiomyopathy • Congestive heart failure • Arrhythmias • Coronary artery disease • Valvular anomaly • Cerebrovascular disease • Peripheral arterial disease Tests: <ul style="list-style-type: none"> • Cumulative dose of anthracyclines • Echocardiogram with ventricular function, ECG in patients at risk and in symptomatic patients • Fasting blood sugar • Fasting lipid profile (including HDL-C, LDL-C and triglycerides) 	All HCT recipients			
		Routine clinical assessment of cardiovascular risk factors		✓	✓
		Education and counseling on “heart healthy” lifestyle (regular exercise, healthy weight, no smoking, dietary counseling) Visit uspreventiveservicestaskforce.org	✓	✓	✓
		Early treatment of cardiovascular risk factors such as diabetes, hypertension and dyslipidemia	✓	✓	✓
		Administration of antibiotics for endocarditis prophylaxis according to American Heart Association guidelines Visit http://circ.ahajournals.org/content/116/15/1736.full.pdf	✓	✓	✓

POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Liver	Complications: <ul style="list-style-type: none"> • GVHD • Hepatitis B • Hepatitis C • Iron overload Tests: <ul style="list-style-type: none"> • Liver function testing (LFT) • Polymerase Chain Reaction (PCR) for hepatitis B or C • Liver biopsy • Serum ferritin • Imaging for iron overload (MRI or SQUID) 	All HCT recipients			
		LFTs; may be performed more frequently as clinically indicated	✓	✓	✓
		Monitor viral load by PCR for patients with known hepatitis B or C, with liver and infectious disease specialist consultation. Consider liver biopsy at 8-10 years after HCT to assess cirrhosis in patients with chronic HCV infection	+	+	+
Renal and genitourinary	Complications: <ul style="list-style-type: none"> • Chronic kidney disease (CKD) • Bladder dysfunction • Urinary tract infections Tests: <ul style="list-style-type: none"> • Urine protein • Serum creatinine • BUN 	All HCT recipients			
		Blood pressure assessment with aggressive hypertension management	✓	✓	✓
		Assess renal function with serum creatinine, BUN and urine protein. Further workup (kidney biopsy or renal ultrasound) for renal dysfunction as clinically indicated	✓	✓	✓
		Avoid nephrotoxins and consider early referral to a nephrologist for evaluation and treatment in patients with progressive CKD	✓	✓	✓

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POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Muscle and connective tissue	Complications: <ul style="list-style-type: none"> Myopathy Fasciitis/scleroderma Polymyositis Tests: <ul style="list-style-type: none"> Evaluate ability to stand from a sitting position Clinical evaluation of joint range of motion 	All HCT recipients			
		Physical activity counseling. Follow general population guidelines for physical activity	✓	✓	✓
		Additional measures for special populations*			
		Frequent clinical evaluation for myopathy by manual muscle tests or by assessing ability to go from sitting to standing position	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids
		Evaluate joint range of motion to detect sclerotic changes. Patients should also be instructed to perform self-assessment of range of motion	✓ GVHD	✓ GVHD	✓ GVHD
Mucocutaneous	Complications: <ul style="list-style-type: none"> Cutaneous sclerosis Genital GVHD Tests: <ul style="list-style-type: none"> Skin exam Pelvic exam 	All HCT recipients			
		Counsel patients to perform routine self-exam of skin and avoid excessive exposure to sunlight without adequate protection	✓	✓	✓
		Annual gynecologic exam in women		✓	✓
		Additional measures for special populations*			
		Consider more frequent gynecologic evaluation based on clinical symptoms	✓ GVHD ✓ TBI	✓ GVHD ✓ TBI	✓ GVHD ✓ TBI

POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Skeletal	Complications: <ul style="list-style-type: none"> • Osteopenia/osteoporosis • Avascular necrosis Tests: <ul style="list-style-type: none"> • Dual photon densitometry • MRI 	All HCT recipients			
		Dual photon densitometry for adult women, all allogeneic HCT recipients and patients who are at high risk for bone loss (e.g., prolonged corticosteroid exposure); subsequent testing determined by defects or to assess response to therapy		✓	+
		Counseling about physical activity, vitamin D and calcium supplementation to prevent loss of bone density	✓	✓	✓
		Additional measures for special populations*			
Nervous system	Complications: <ul style="list-style-type: none"> • Leukoencephalopathy • Neuropsychological and cognitive deficits • Late infections • Calcineurin neurotoxicity • Peripheral neuropathy Tests: <ul style="list-style-type: none"> • MRI • Neuropsychological testing 	All HCT recipients			
		Clinical evaluation for symptoms and signs of neurologic dysfunction. Diagnostic testing (e.g., radiographs, nerve conduction studies) for those with symptoms or signs	+	✓	✓
		Evaluate for changes in cognitive function, which may be subtle in adults	+	✓	✓
		Additional measures for special populations*			
		Assessment for cognitive development milestones		✓ Pediatric	✓ Pediatric

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POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Endocrine	Complications: <ul style="list-style-type: none"> Hypothyroidism Hypoadrenalism Hypogonadism Growth retardation Tests: <ul style="list-style-type: none"> Thyroid function tests FSH, LH, testosterone Growth velocity in children 	All HCT recipients			
		Thyroid function testing — additional testing if relevant symptoms develop		✓	✓
		Clinical and endocrinologic gonadal assessment for post-pubertal women, subsequent follow-up based on menopausal status		✓	+
		Gonadal function in men, including FSH, LH, and testosterone, should be assessed as warranted by symptoms		+	+
		Additional measures for special populations*			
		Clinical and endocrinologic gonadal assessment for pre-pubertal boys and girls within 1 year of transplant, with further follow-up as determined in consultation with a pediatric endocrinologist	✓ Pediatric	✓ Pediatric	✓ Pediatric
		Monitor growth velocity in children; assessment of thyroid, and growth hormone function if clinically indicated		✓ Pediatric	✓ Pediatric
		Consider stress doses of corticosteroids during acute illness for patients who have received chronic corticosteroids	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids
		Slow terminal tapering of corticosteroids for those with prolonged exposure	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids	✓ GVHD ✓ Steroids

POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Second cancers	Complications: <ul style="list-style-type: none"> • Solid tumors • Hematologic malignancies • Post-transplant lymphoproliferative disorder (PTLD) Tests: <ul style="list-style-type: none"> • Mammogram • Screening for colon cancer (e.g., colonoscopy, sigmoidoscopy, fecal occult blood testing) • Pap smear 	All HCT recipients			
		Counsel patients about risks of secondary malignancies and encourage them to perform self-exam (e.g., skin, testicles/genitalia) and counsel to avoid high-risk behaviors (e.g., smoking)		✓	✓
		Screen for second cancers — follow general population recommendations for cancer screening		✓	✓
		Additional measures for special populations*			
		Clinical and dental evaluation with particular attention toward oral and pharyngeal cancer	✓ GVHD	✓ GVHD	✓ GVHD
		Screening mammography in women starting at age 25 or 8 years after radiation exposure, whichever occurs later but no later than age 40	✓ Women with exposure to TBI/chest irradiation		

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POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Tissues/Organs	Complications and Tests	Preventive Measures	Recommended Timing		
			6 mo.	12 mo.	Annually
Psychosocial and sexual	Complications: <ul style="list-style-type: none"> • Depression • Anxiety • Fatigue • Sexual dysfunction Tests: <ul style="list-style-type: none"> • Psychological evaluation 	All HCT recipients			
		Clinical assessment throughout recovery period, with mental health professional counseling recommended for those with recognized symptoms	✓	✓	✓
		Regularly assess level of spousal/caregiver psychological adjustment and family functioning. Encourage robust support networks	✓	✓	✓
		Query adults about sexual function	✓	✓	✓
Fertility	Complications: <ul style="list-style-type: none"> • Infertility Tests: <ul style="list-style-type: none"> • FSH, LH levels 	All HCT recipients			
		Consider referral to appropriate specialists for patients who are contemplating a pregnancy or are having difficulty conceiving		+	+
		Sexual function assessment. Counsel sexually active patients in the reproductive age group about birth control post-HCT	✓	✓	✓
General health		All HCT recipients			
		Recommended screening as per general population: hypertension, hypercholesterolemia, diabetes, depression, sexually transmitted diseases, osteoporosis (in women), cancer screening. For details visit uspreventiveservicestaskforce.org	✓	✓	✓

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POST – AUTOLOGOUS BMT RECOMMENDED FOLLOW UP CARE²

Vaccine	Recommended for use after HCT	Time post-HCT to initiate vaccine	No. of doses ^a
Pneumococcal conjugate (PCV)	Yes	3-6 months	3-4 ^b
Tetanus, diphtheria, acellular pertussis ^c	Yes	6-12 months	3 ^d
<i>Haemophilus influenzae</i> conjugate	Yes	6-12 months	3
Meningococcal conjugate	Follow country recommendations for general population	6-12 months	1
Inactivated polio	Yes	6-12 months	3
Recombinant hepatitis B	Follow country recommendations for general population	6-12 months	3
Inactivated influenza	Yearly	4-6 months	1-2 ^e
Measles-mumps-rubella (live) ^{f,g}	Measles: All children and seronegative adults	24 months	1-2 ^h

See references on previous page for vaccinations considered optional or not recommended for HCT recipients and for vaccinations for family, close contacts and health care workers.

^a A uniform specific interval between doses cannot be recommended, as various intervals have been used in studies. As a general guideline, a minimum of 1 month between doses may be reasonable.

^b Following the primary series of three PCV doses, a dose of the 23-valent polysaccharide pneumococcal vaccine (PPSV23) to broaden the immune response might be given. For patients with chronic GVHD who are likely to respond poorly to PPSV23, a fourth dose of the PCV should be considered instead of PPSV23.

^c DTaP (diphtheria tetanus pertussis vaccine) is preferred, however, if only Tdap (tetanus toxoid-reduced diphtheria-toxoid reduced acellular pertussis vaccine) is available (for example, because DTaP is not licensed for adults), administer Tdap. Acellular pertussis vaccine is preferred, but the whole-cell pertussis vaccine should be used if it is the only pertussis vaccine available.

^d See references on previous page for consideration of an additional dose(s) of Tdap for older children and adults.

^e For children <9 years of age, two doses are recommended yearly between transplant and 9 years of age.

^f Measles, mumps and rubella vaccines are usually given together as a combination vaccine. In females with pregnancy potential, vaccination with rubella vaccine either as a single or a combination vaccine is indicated.

^g Not recommended <24 months post-HCT, in patients with active GVHD, and in patients on immune suppression.

^h In children, two doses are favored.

STATE OF TELEMEDICINE³

- 60% of all healthcare institutions use telemedicine
- 40% - 50% of all U.S. hospitals use telemedicine
- Medicaid has no restrictions for state coverage.
- Medicare will only reimburse when the beneficiary is in a rural originating site.

TELEMEDICINE IN KANSAS⁴

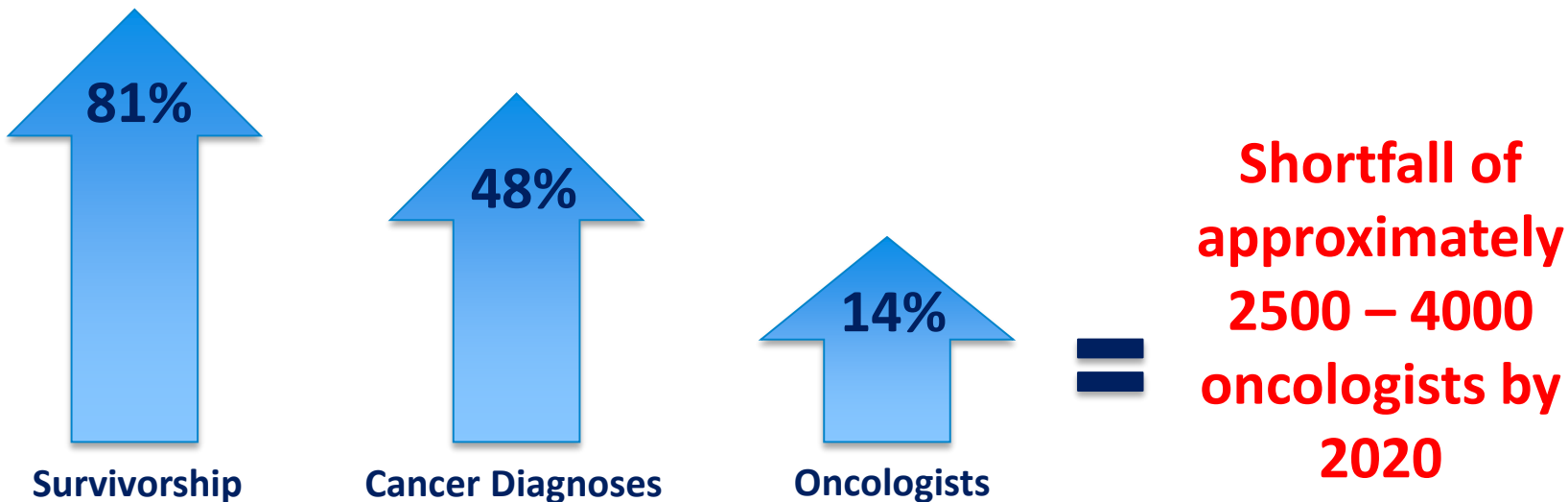
“Telemedicine,” including “telehealth” means the delivery of healthcare services or consultations while the patient is at an originating site and the healthcare provider is at a distant site. Telemedicine shall be provided by means of real-time two-way interactive audio, visual, or audio-visual communications.

TELEMEDICINE IN KANSAS⁴

“Telemedicine” does not include communication between:

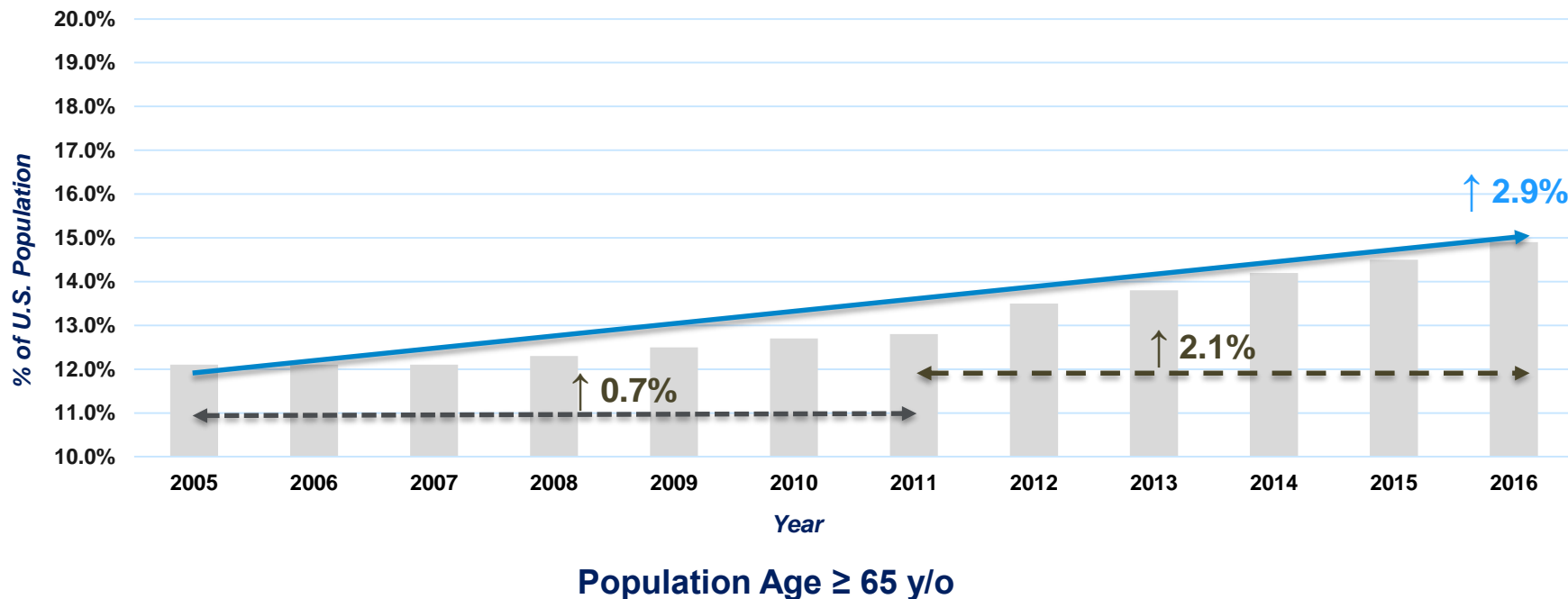
- Healthcare providers that consists solely of a telephone voice-only conversation, email or facsimile transmission; or
- A physician and a patient that consists solely of an email or facsimile transmission

1. Predicted shortage of oncologists across the United States



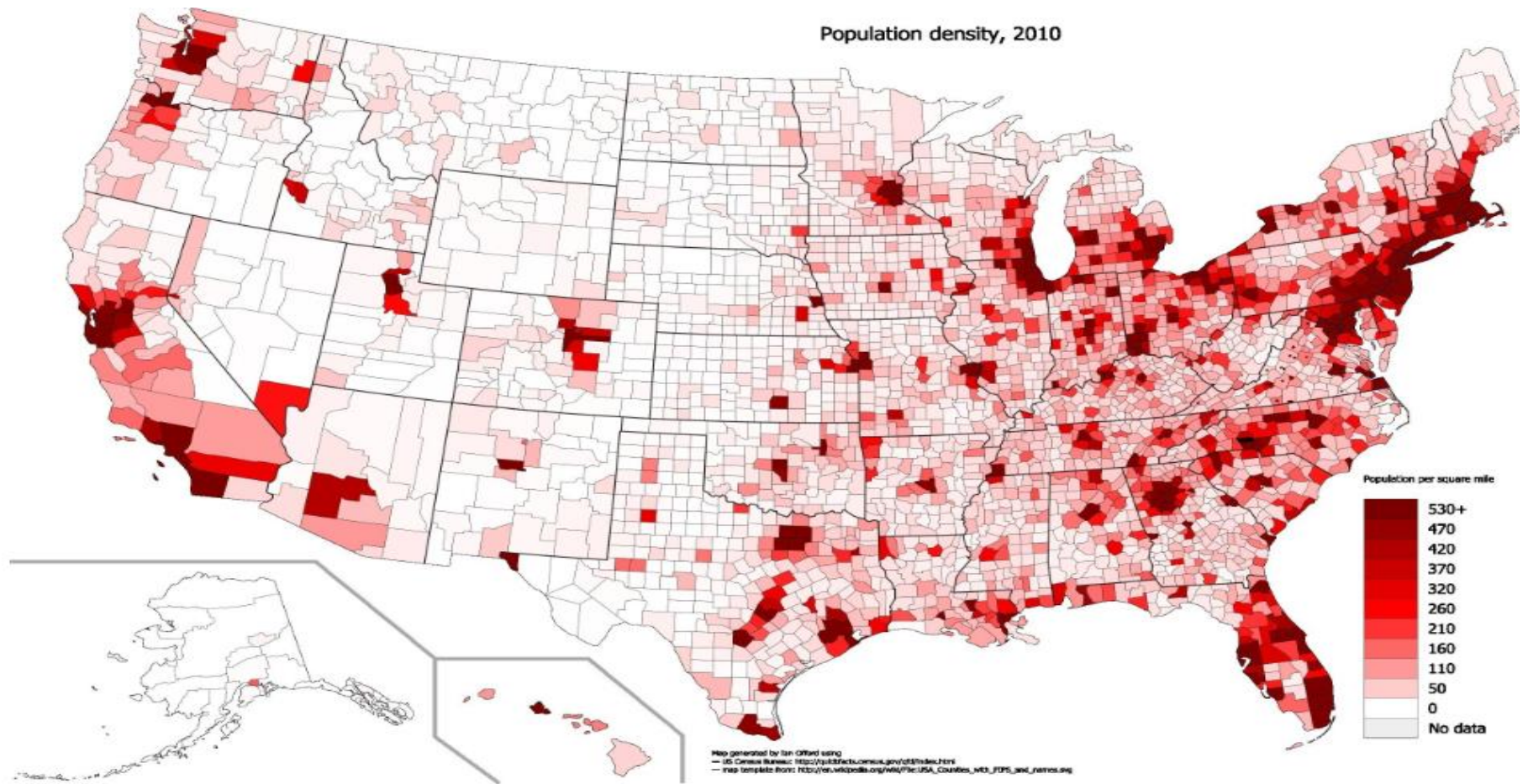
TELEMEDICINE IN ONCOLOGY^{5,6,7}

2. Aging population

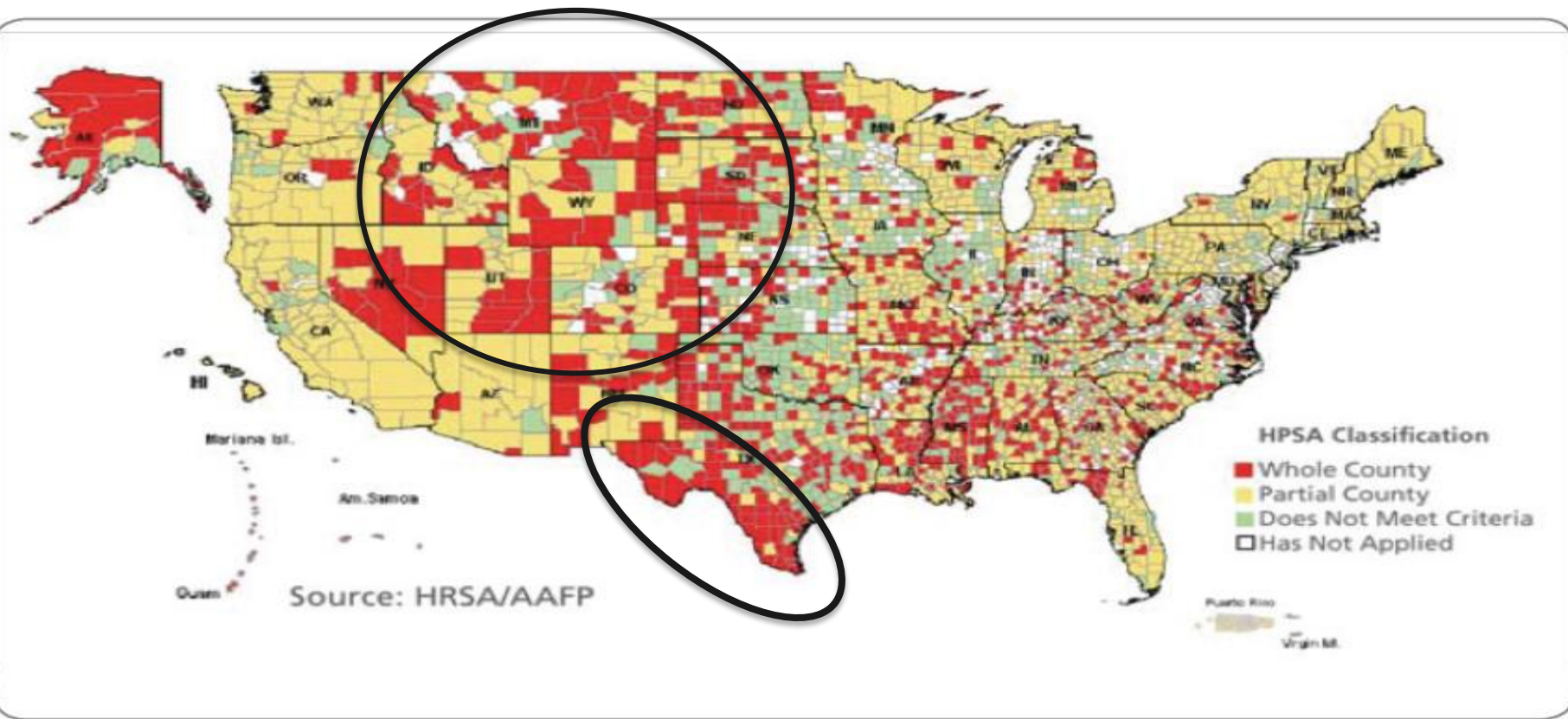


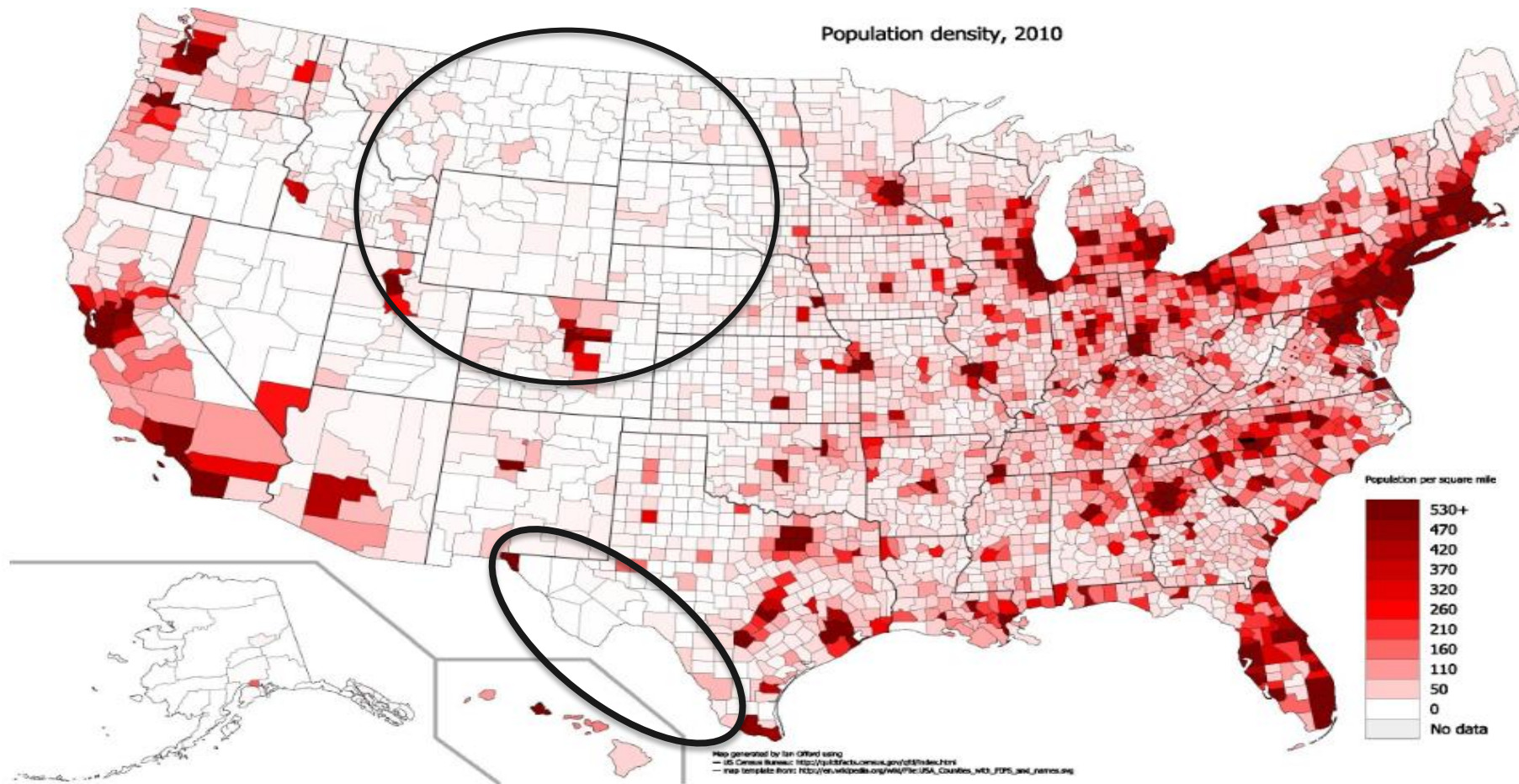
3. “Oncology healthcare workforce and population geographic mismatch”

Population density, 2010



Federally Designated Health Professional Shortage Areas by County





TELEMEDICINE AT RMC – *CURRENT STATE*

- Management of complex blood cancers and benign hematology
 - Over 200 telemedicine visits since inception
- Offer state of art opinions close to home
- Offers collaboration for clinical research trials
 - Eligibility assessment
 - Symptom management
 - Trial follow-up

TELEMEDICINE AT RMC – *FUTURE STATE*

- Inpatient evaluation/assessments
- Post – transplant follow-up care
 - Autologous after Day +30
 - Allogeneic after Day +100
- Potential collaboration in genomics research using EMR capabilities through Central Care

CITATIONS

1. Be The Match® Disease-Specific HCT Indications and Outcome Data. <https://bethematchclinical.org/transplant-indications-and-outcomes/disease-specific-indications-and-outcomes>
2. Be The Match® 2019 Long Term Survival Guidelines. *Post-Transplant Care Recommendations*. <https://bethematchclinical.org/resources-and-education/materials-catalog/hct-guidelines-for-referral-timing-and-post-transplant-care/>
3. Tuckerson R.V., Edmunds M., Hodgkins M.L. (2019). Telehealth. *N Engl J Med*, 377: 1585 – 1592.
4. KB HB 2028 (2018)
5. Sirintrapun S.J., Lopez A.M. (2018). Telemedicine in cancer care. *American Society of Clinical Oncology Educational Book*, 38: 540 – 545.
6. Erikson C., Slasberg E., Forte G., et al. (2007). Future supply and demand of oncologists: Challenges to assuring access to oncology services. *J Oncol Pract*, 3: 79 – 86.
7. U.S. Census Bureau. www.census.gov
8. The Counsel of State Governments. Health Care Workforce Shortages Critical in Rural America. www.knowledgecenter.csg.org/kc/content/health-care-workforce-shortages-critical-rural-america



THANK YOU!