



**Comments on Training and  
Experience Requirements for  
Authorized Users of  
Alpha and Beta Emitters**

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March 17, 2016**

# Background

- **RIT of lymphoma with beta emitters approved about 14 years ago.**
- **Two agents**
  - $^{90}\text{Y}$  ibritumomab tiuxetan (Zevalin®)**
  - $^{131}\text{I}$  tositumomab (Bexxar®).**

# **Background**

**Use of both agents**

**Peaked shortly after introduction**

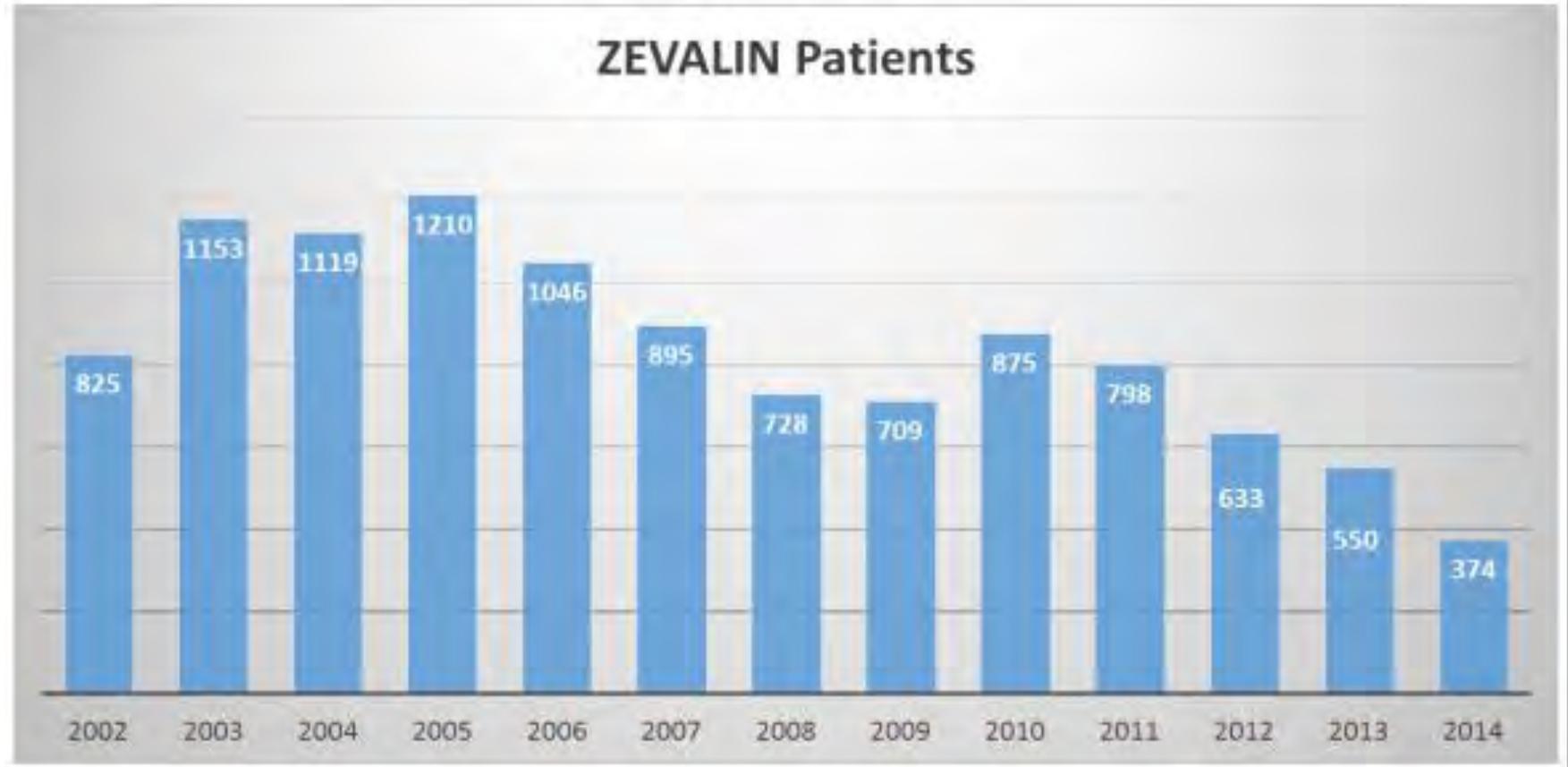
**Steady decline since**

**Bexxar® withdrawn in 2014**

**Lack of use**

**< 75 patients treated in 2014**

# Background



Adapted from Spectrum Pharmaceuticals, ACMUI meeting October 2015

# **Background**

**Why has RIT use declined despite favorable clinical results?**

**-Direct effect of the change in AU T&E requirements that went into effect in 2006?**

**-ACMUI subcommittee formed**

# **ACMUI Subcommittee on T&E**

## **Charge 1**

**Determine if current requirement (700 hours for T&E) for AU of alpha & beta emitters places hardship on patient community & make recommendations for ACMUI action.**

# **ACMUI Subcommittee on T&E**

## **Charge 2**

**Establish recommendation for total number of hours of T&E for AU's of such emitters that appropriately balances safety with reasonable patient access**

# **Factors Possibly Accounting for Decreased RIT Use**

- **Lack of knowledge**
- **Competition**
- **Shortage of AU's**

# Factors Possibly Accounting for Decreased RIT Use

Institution	Time Period	Total number of Therapies
<b>Memorial Sloan Kettering Cancer Ctr. (NY)</b>	<b>2009-2014</b>	<b>190</b>
<b>University of Maryland (Baltimore)</b>	<b>2002-2014</b>	<b>25</b>
<b>North Shore LIJ Health System (NY)</b>	<b>2005-2014</b>	<b>49</b>
<b>Washington University/Barnes-Jewish Hospital (St. Louis)</b>	<b>2004-2014</b>	<b>55</b>

Adapted from Palestro ACMUI meeting Oct 2015

# **Factors Possibly Accounting for Decreased RIT Use**

- **Explanation for decreased RIT use likely multifactorial**
- **Shortage of AU's not the only explanation**

**Regardless, why not reduce T&E requirements?**

# **Reducing AU T&E Requirements for Alpha and Beta Emitters**

- **Excellent safety record for RIT  
80 hours T&E for  $^{131}\text{I}$  therapy**
- **Consequences of  
misadministration of RIT vs  $^{131}\text{I}$**

# **ACMUI Subcommittee on T&E**

## **Charge 1**

**Determine if current requirement (700 hours for T&E) for AU of alpha & beta emitters places hardship on patient community ...**

**No change in T&E requirements**

# **ACMUI Subcommittee on T&E**

## **Charge 2**

**Establish recommendation for total number of hours of T&E ...**

**Time for thorough review of T&E  
Nearly 15 years since last review  
New radiopharmaceuticals  
New educational paradigm**

# **ACMUI Subcommittee on T&E**

## **Subcommittee Recommendation**

**Establish standing subcommittee to periodically review T&E requirements currently in effect making recommendations for changes as warranted**

**Subcommittee established Feb 2016**

# **ACMUI's Position**

- **The report and its recommendations were unanimously approved by the full Committee on March 10, 2016.**

# **Acronyms**

**ACMUI: Advisory Committee on  
Medical Uses of Isotopes**

**AU: Authorized user**

**<sup>131</sup>I: Iodine-131**

**RIT: Radioimmunotherapy**

**T&E: Training and experience**

**<sup>90</sup>Y: Yttrium-90**