



Health Solutions

Communication Toolkit for Product X

Prepared by RTI Health Solutions
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The power of knowledge.
The value of understanding.

Contents

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SECTION 1

Introduction

Key objectives

Compelling and comprehensive modules with different top-line value messages and in-depth evidence to support communication with payer stakeholders on the existing unmet needs in Disease X and the potential value of Product X

Summary of payer-relevant background information on the disease and unmet needs to set the scene for Product X

Synthesis of the key evidence of Product X in Disease X to demonstrate to payers the value and position of Product X

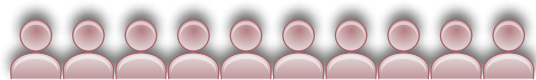
Repository for pertinent information to be provided to payer stakeholders

SECTION 2

Executive Summary

US Impact of HIV

- The Centers for Disease Control and Prevention (CDC) estimates that more than 1 million people are living with HIV in the US
- 20% of people living with HIV are unaware of their infection



More than 1 million people
are living with HIV in the US

1 in 5 people are living with HIV



are unaware of their infection

Every 9.5 minutes



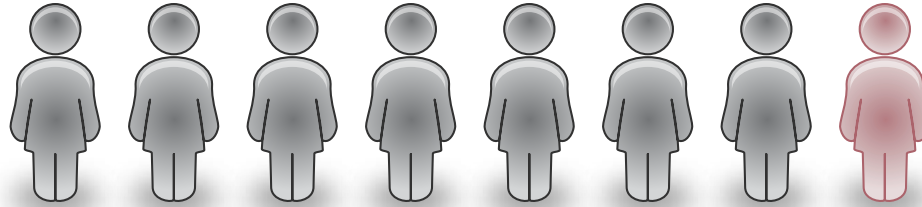
someone in the US is
infected with HIV

EXAMPLE ONLY

Breast Cancer: The Disease and Its Burden

Most diagnosed breast cancers are invasive at time of diagnosis

- 1 in 8 women (13%) in the US will have breast cancer during their lifetime



- About 70% of all invasive breast cancers are positive for ER and/or PgR expression at the time of diagnosis
- 15-25% of all breast cancers are HER2 overexpressing
- Postmenopausal women are more likely to be HR+
- About 40% of diagnosed patients may develop MBC
- Treatment for MBC is palliative, and median life expectancy after recurrence is 24-30 months or less
- Mean per patient per month costs (2004 US\$) attributable to breast cancer were \$2,896

1. American Cancer Society. Breast Cancer Facts and Figures 2007-2008. American Cancer Society. www.cancer.org/Cancer/BreastCancer/DetailedGuide/breast-cancer-key-statistics
3. Barron et al. Breast Cancer Res Treat. 2008;109:367-77
4. Dobrescu et al. ER and PR Expression in Breast Ductal Carcinoma In Situ by Immunohistochemical Staining in ER/PgR-Negative Invasive Breast Cancer. ISRN Oncology. Vol. 2011, Article ID 673790. <http://www.isrn.com/journals/oncology/2011/673790/>.

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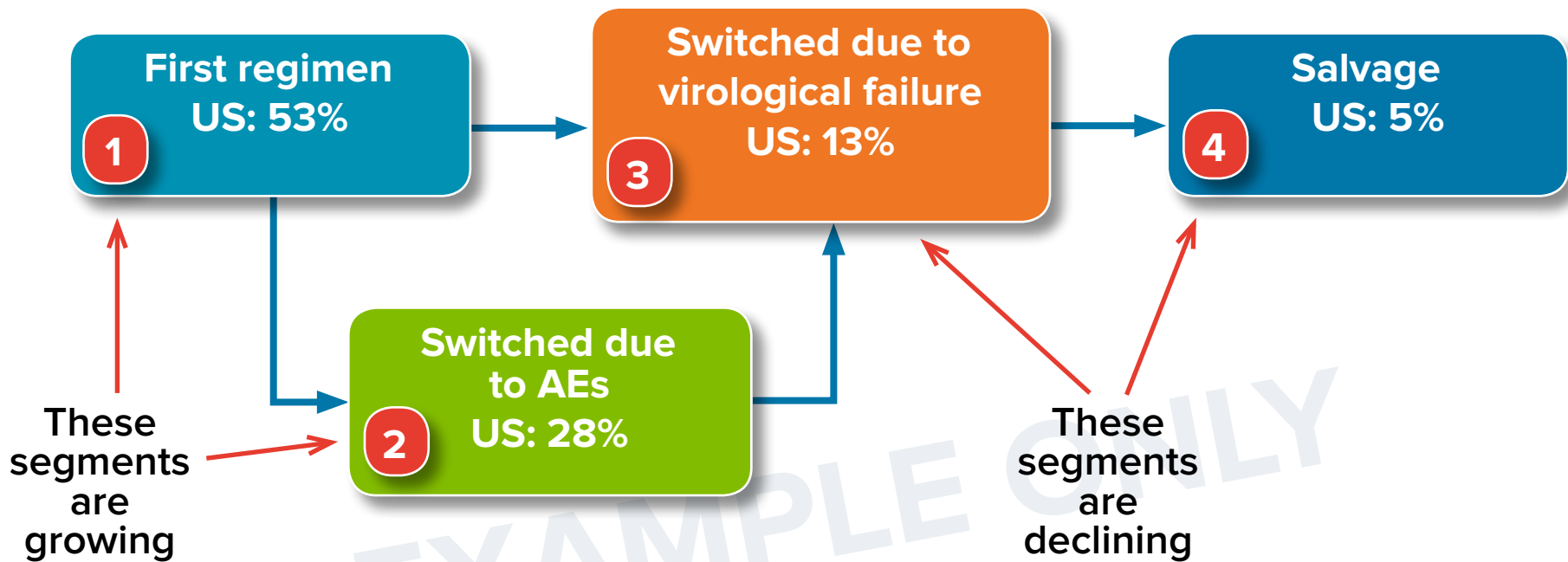
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Some explanation about this chart

- could be here

- Introductions of new antiretrovirals with better tolerability and strong antiretroviral activity have led to a reduction in the rates of virologic failure and an increase in the number of patients remaining on their first-ever regimen
- In the US:
 - 81% have never virologically failed
 - 53% are on their first-ever regimen
 - 28% have switched for tolerability, highlighting the need for more tolerable treatments
- Due to improvements in therapy, the number of patients in the salvage segment (virologically failed and on 4+ antiretrovirals) is extremely small and diminishing in size

Current Unmet Needs in HIV

- Despite remarkable improvements in HIV treatment and prevention, economic and social barriers that result in continued morbidity, mortality, and new HIV infections persist
- Antiretroviral therapy (ART) has dramatically reduced HIV-associated morbidity and mortality and has transformed HIV into a chronic, manageable condition

Poor Adherence

- Adherence to HIV treatments remains suboptimal among both commercially insured and Medicaid HIV patients
 - 59% of commercially insured patients achieved $\geq 80\%$ adherence, compared with 42% of Medicaid patients
 - Among commercially insured and Medicaid patients, treatment-experienced patients were more likely to be adherent than treatment-naïve patients

- Poor adherence may be attributable to tolerability issues
 - High switch rates
 - High discontinuation
- High adherence is required to prevent failure of virologic suppression, development of drug resistance, and permanent loss of therapeutic options
- In a study by Maggiolo et al.,^a the risk of virologic failure was:
 - 2.4% in patients with cART adherence of > 95%
 - 4.3% in patients with adherence rates of 86%-95%
 - 12.2% in patients with adherence rates of 76%-85%
 - 17.4% in patients with adherence rates of ≤ 75%
- World Health Organization (WHO) guidelines^b state that adherence of at least 95% is desirable over long periods of time

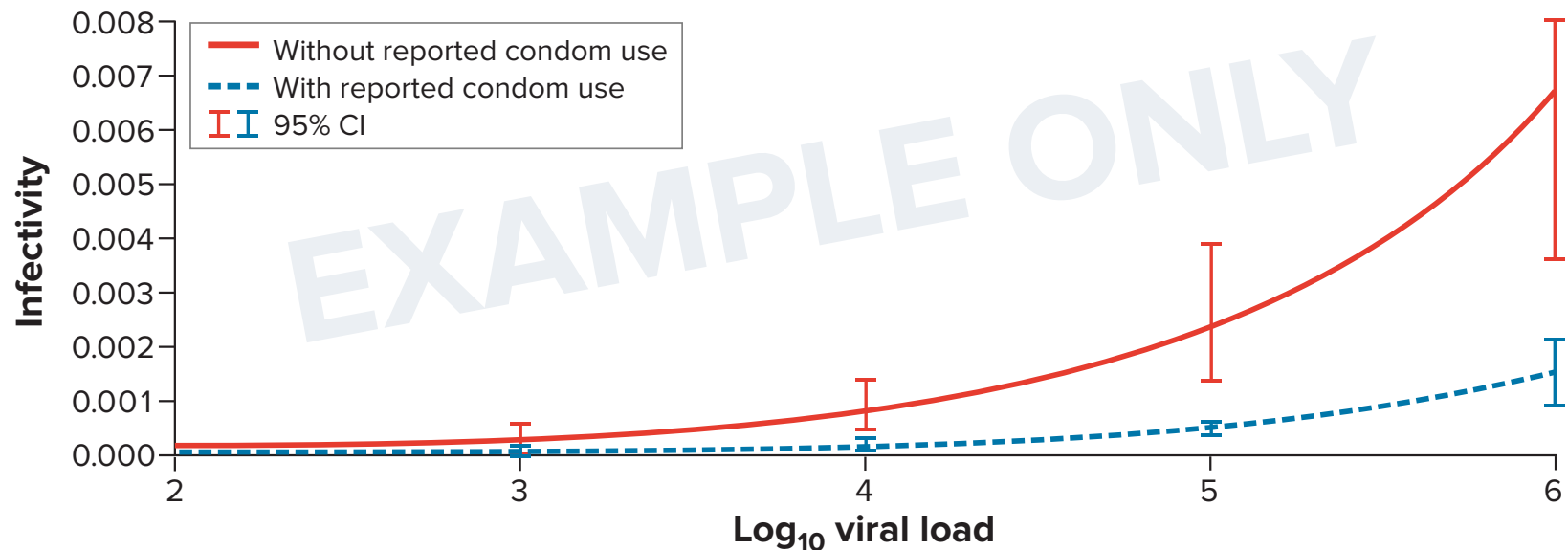
cART = combination antiretroviral therapy; NNRTI = nonnucleoside reverse-transcriptase inhibitor; PI = protease inhibitor.

^aMaggiolo et al. Clin Infect Dis. 2005 Jan 1;40(1):158-63. Note: Study was conducted in Italy.

^bWHO. www.who.int/hiv/pub/guidelines/artadultguidelines.pdf.

- ART adherence among commercially insured and Medicaid HIV patients in the US is associated with improved economic outcomes
 - 29% and 31% reductions, respectively, in nonpharmacy costs ($P < 0.0001$)
 - 43% and 49% reductions, respectively, in hospitalizations ($P < 0.0001$)
 - 41% and 26% reductions, respectively, in emergency department (ED) visits ($P < 0.0001$)

An Increase in Viral Load Increases the per-Act Risk of Transmission by 2.9-Fold



CI = confidence interval.

Figure adapted from Hughes et al. J Infect Dis. 2012;205:358-65.

Switching

- Switching among commercially insured and Medicaid HIV patients results in higher nonpharmacy and total costs versus nonswitchers
- Switching early (≤ 90 days) results in higher nonpharmacy and total costs versus nonswitchers in both commercially insured and Medicaid HIV patients
- Switching results in higher nonpharmacy and total costs versus nonswitchers
 - Third-agent switching: costs per person-year were significantly higher in second- and third-line treatment as compared with first-line treatment

EXAMPLE ONLY

Summary

- HIV leads to substantial disease burden
- Adherence is key to treatment success
 - Poor adherence may lead to resistance and greater economic burden
- Currently available antiretrovirals may be suboptimal, leading to efficacy/safety trade-offs
- ART has transformed HIV into a chronic disease, but it has a substantial cost and is associated with new burdens and costs such as HAART–related AEs, virologic failure, and viral resistance

AE = adverse event; HAART = highly active antiretroviral therapy.

Product Value

Market Access Overview

Key Issues in the US Health Care Market

- The Patient Protection and Affordable Care Act is designed to expand health coverage to 32 million uninsured Americans by 2019; the act makes significant changes to public and private health insurance systems that will affect providers of HIV care^a
- Access to antiretrovirals through Medicare and Medicaid is worsening, and deficiencies in AIDS Drug Assistance Programs (ADAPs) are increasing^b
- The Patient Protection and Affordable Care Act also phases out the Medicare Part D prescription drug benefit “donut hole,” giving Medicare enrollees living with HIV and AIDS the peace of mind that they will be better able to afford their medications^c

^a Martin and Schackman. J Acquir Immune Defic Syndr 2012;60:72.

^b Sherer. Sex Transm Infect. 2012;88(2):106-11.

^c AIDS.gov. <http://aids.gov/federal-resources/policies/health-care-reform/>.

Competitor Overview

Currently Available Drugs May Be Suboptimal, Leading to Efficacy/Safety Tradeoffs

Key Limitations	Drug 1	Drug 2	Drug 3	Drug 4
Limitation 1	✓	✓	✓	✓
Limitation 2				
Limitation 3				
Limitation 4				
Limitation 5				
Limitation 6				
Limitation 7				
Limitation 8				

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