INDIVIDUALIZING HIV CARE
to Optimize Patient Outcomes

This continuing medical education activity is provided by
THE UNIVERSITY OF CHICAGO PRITZKER SCHOOL OF MEDICINE

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This activity is supported by an educational grant from Janssen Therapeutics, Division of Janssen Products, LP.

Learning Objectives

- Investigate the impact of antiretroviral therapy selection on factors that influence therapeutic effectiveness in patients with HIV, such as adherence, drug resistance, and safety.
- Examine treatment regimens that individualize treatment and meet the clinical and social needs of the patient.
- Evaluate the suitability of different classes of antiretroviral drugs for long-term HIV treatment.
- Assess the factors influencing the below-target outcomes of national programs such as the National HIV/AIDS Strategy (NHAS).
- Assess HIV preventative measures, as well as diagnostic and care initiatives, provided through the Affordable Care Act and how they can be effectively incorporated into managed care programs.
- Describe populations at high risk for HIV and strategies to engage and retain them in the care continuum.

Faculty

Richard A. Elion, MD
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Co-Director, DC Dept of Health STD Research Program
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Advances in HIV Treatment and Management

Richard A. Elion, MD

Associate Clinical Professor of Medicine

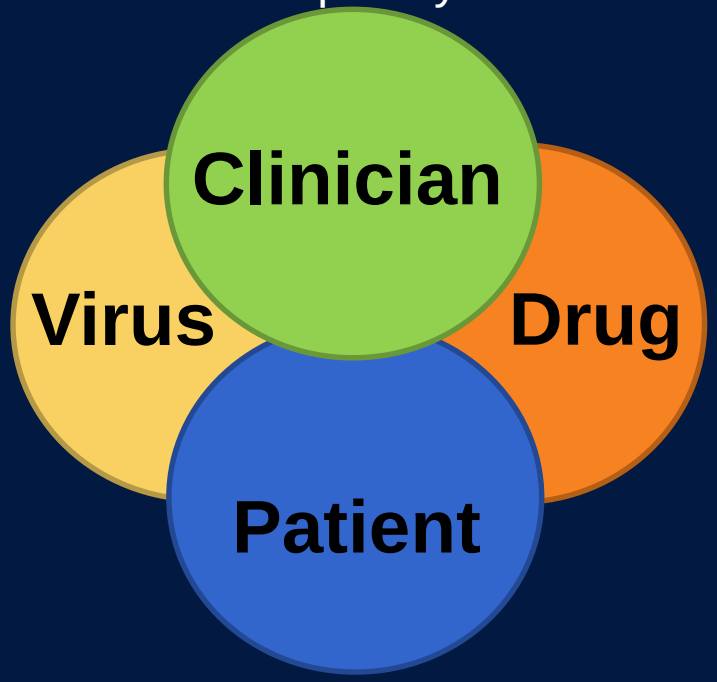
George Washington University School of Medicine

Co-Director, DC Department of Health STD Research Program

Washington, DC

Determinants of Successful ART

Clinician experience
Communication skills
Multidisciplinary team



Replication rate
(Viral load)
Mutation rate
(Resistance)
Tropism
Latent HIV reservoirs

Potency
Pharmacokinetics
(dosage schedule)
Tolerability
Toxicity
Convenience
Resistance

Adherence
Access to care
Access to medication
Life situation
Disease stage

When to Start ART: Global Consensus

	AIDS or HIV-related Symptoms	CD4 Count (cells/mm^3)			
		<200	200–350	350–500	>500
United States DHHS (updated 2016)	Yes	Yes	Yes	Yes	Yes
IAS-USA (2014)	Yes	Yes	Yes	Yes	Yes
British HIV Association (2015)	Yes	Yes	Yes	Yes	Yes
European AIDS Clinical Society (2015)	Yes	Yes	Yes	Yes	Yes
WHO (2015)	Yes	Yes	Yes	Yes	Yes

DHHS = Department of Health and Human Services; WHO = World Health Organization.

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 1, 2016; Günthard HF, et al. *JAMA.* 2014;312:410-425; EACS. http://www.eacsociety.org/files/2015_eacsguidelines_8_0-english_rev-20160124.pdf. Accessed May 4, 2016; BHIVA. http://www.bhiva.org/documents/Guidelines/Treatment/2016/treatment-guidelines-2016-interim-update.pdf. Accessed May 4, 2016; WHO. http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en. Accessed May 4, 2016.

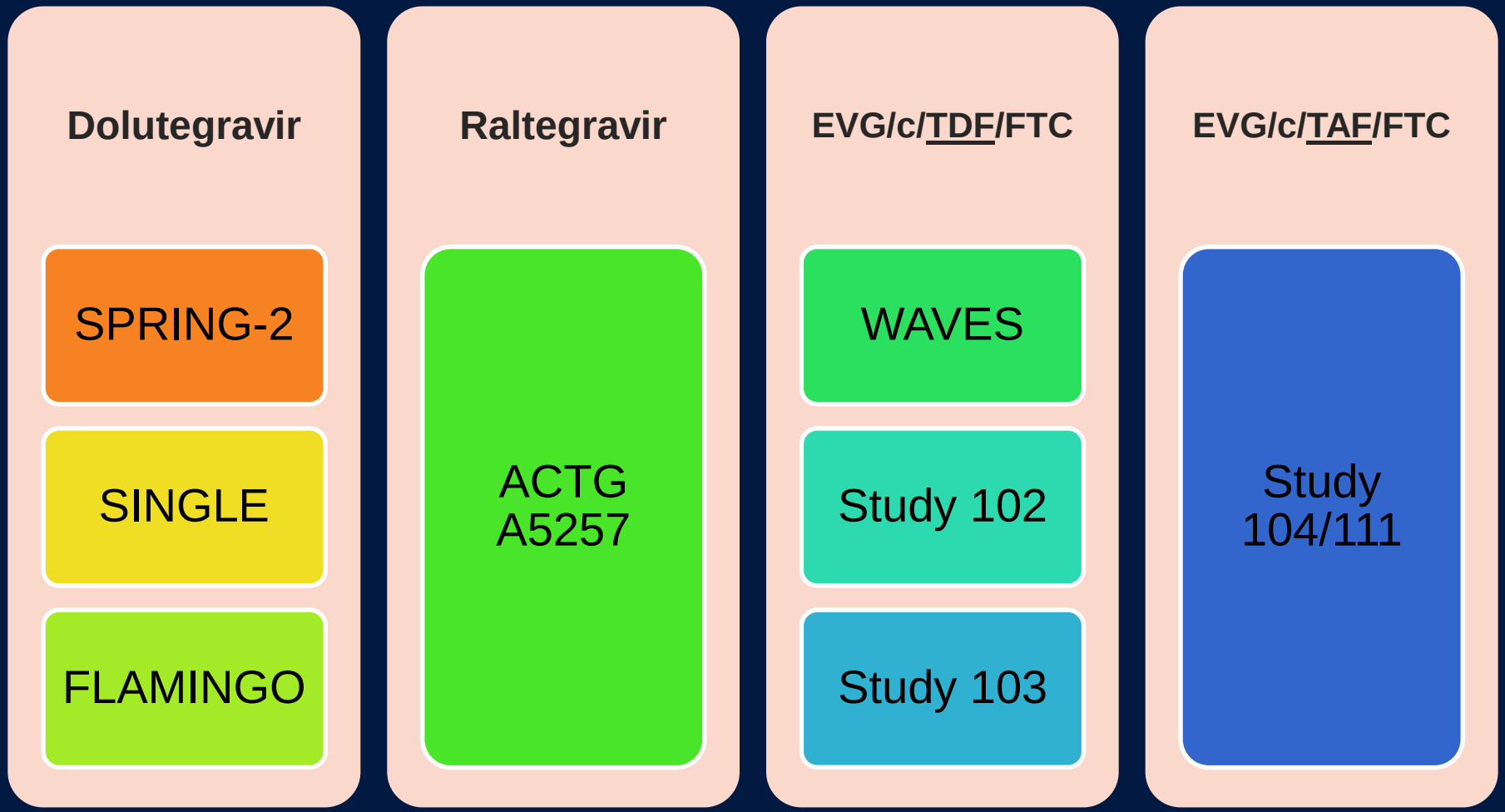
Guidelines for Treatment-Naive HIV Patients

Regimen	DHHS[1]	IAS-USA[2]	BHIVA[3]	EACS[4]	GeSIDA[5]
DTG/3TC/ABC	Recommended	Recommended	Recommended	Recommended	Recommended
DTG + TDF/FTC	Recommended	Alternative	Recommended	Recommended	Recommended
DTG + FTC/TAF	Recommended	Recommended	Not included	Not included	Not included
EVG/c/TDF/FTC	Recommended	Alternative	Recommended	Recommended	Alternative
EVG/c/FTC/TAF	Recommended	Recommended	Not included	Not included	Recommended
RAL + FTC/TAF	Recommended	Recommended	Not included	Not included	Not included
RAL + TDF/FTC	Recommended	Alternative	Recommended	Recommended	Recommended
ATV/r + TDF/FTC	Alternative	Alternative	Recommended	Alternative	Alternative
DRV/r + TDF/FTC	Recommended	Alternative	Recommended	Recommended	Alternative
DRV/r + FTC/TAF	Recommended	Alternative	Not included	Not included	Not included
RPV/TDF/FTC	Alternative	Alternative	Recommended	Recommended	Alternative

Recommended Alternative Not included

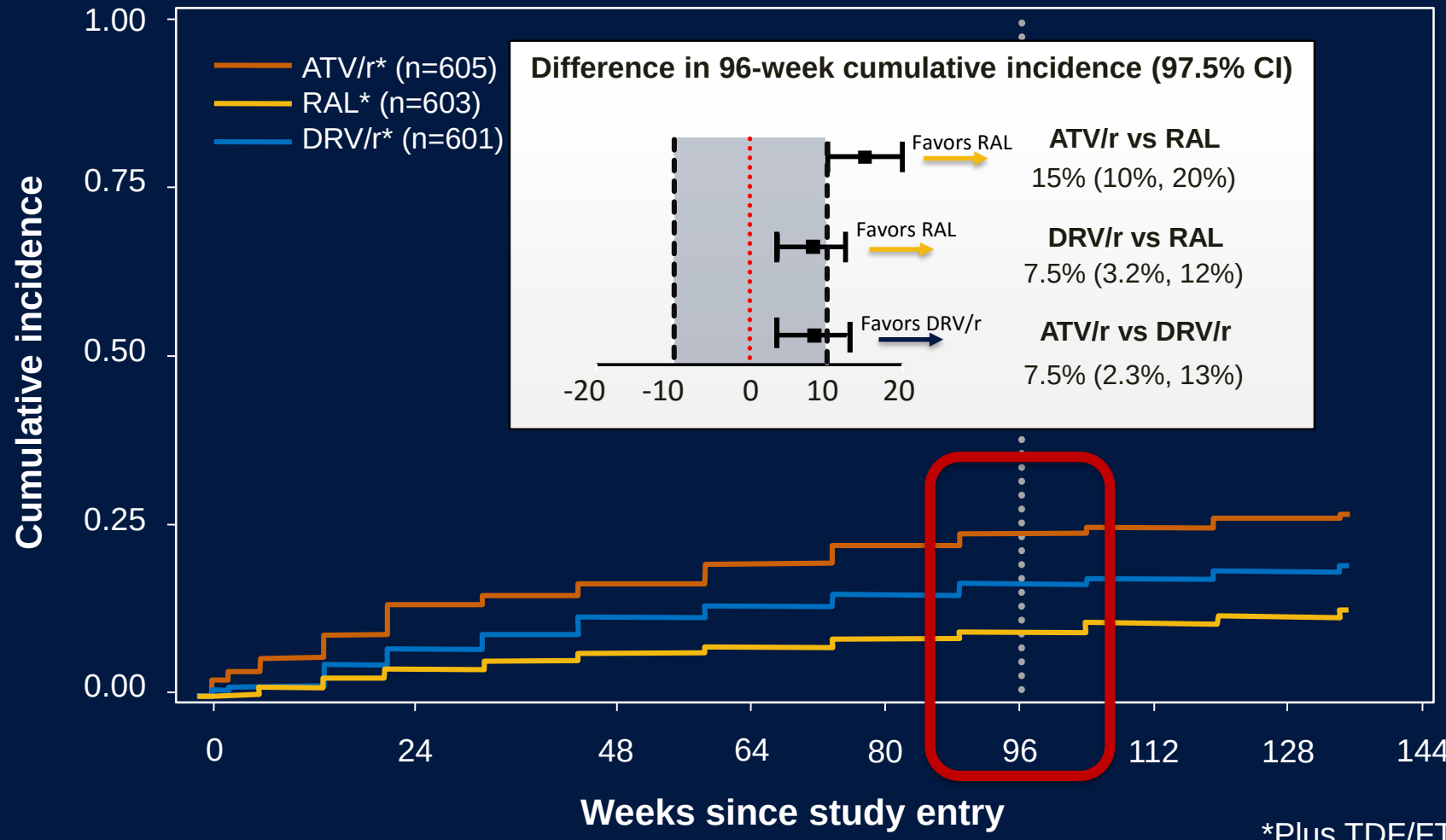
1. DHHS. https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 2, 2016.
2. Günthard HF, et al. *JAMA*. 2016;316:191-210.
3. BHIVA. http://www.bhiva.org/guidelines.aspx. Accessed November 2, 2016.
4. EACS. http://www.eacsociety.org/files/guidelines_8_0-english_web.pdf. Accessed November 2, 2016.
5. AIDS Study Group (GeSIDA), et al. *Enferm Infecc Microbiol Clin*. 2016;34:439-451.

Evidence on Recommended First-Line ARV Therapy



Raffi F, et al. *Lancet*. 2013;381:735-743; Raffi F, et al. *Lancet Infect Dis*. 2013;13:927-935; Walmsley SL, et al. *N Engl J Med*. 2013;369:1807-1818; Clotet B, et al. *Lancet*. 2014;383:2222-2231; Molina JM, et al. *Lancet HIV*. 2015;2:e127-136.; Lennox JL, et al. *Ann Intern Med*. 2014;161:461-471; Squires K, et al. *Lancet HIV*. 2016;3:e410-e420; Wohl DA, et al. J *Acquir Immune Defic Syndr*. 2014;65:e118-e120; Clumeck N, et al. *J Acquir Immune Defic Syndr*. 2014;65:e121-e124; Sax PE, et al. *Lancet*. 2015; 385:2606-2615.

ACTG 5257: RAL is Superior to DRV/r, Which is Superior to ATV/r



*Plus TDF/FTC

- Consistent results seen with time to loss of virologic response (TLOVR) at a 200-copies/mL threshold.

Lennox JL, et al. *Ann Intern Med*. 2014;161:461-471.

Results of ACTG 5257 Driven by Regimen Tolerability

	ATV/r + TDF/FTC N=605	DRV/r + TDF/FTC N=601	RAL + TDF/FTC N=603
Any toxicity/discontinuations	95 (15.7%)	32 (5.3%)	8 (1.3%)
Jaundice or hyperbilirubinemia	47	0	0
Nausea or other GI toxicities	25	14	2
Hepatic toxicity	4	5	1
Skin toxicity	7	5 (1 Stevens-Johnson)	2
Metabolic toxicity	6	2	0
Renal toxicity	4	0	0
Abnormal chemistry/ hematology finding	0	2	0
Other	2	4	3

Lennox JL, et al. *Ann Intern Med*. 2014;161:461-471.

ACTG 5257: Boosted PI Regimens had Lower Rates of Resistance than RAL

Genotypic Analysis for Resistance at Virologic Failure	ATV/r + TDF/FTC N=605	DRV/r + TDF/FTC N=601	RAL + TDF/FTC N=603
Virologic failure	95	115	85
Genotype available	75	99	65
Any resistance detected	9	4	18
PI resistance	0	0	0
NRTI-only resistance • FTC • TDF • FTC and TDF	8 5 2 1	3 3 0 0	7 7 0 0
INI-only resistance*	1	1	1
NRTI and INI resistance • FTC and RAL • FTC, TDF, and RAL	0	0	10 7 3

* Emtricitabine resistance= M184V (21 subjects), M184I (4 subjects), or M184V/I (1 subject).

Lennox JL, et al. *Ann Intern Med*. 2014;161:461-471.

DHHS: Which Patients Should Start a Boosted PI as Initial Therapy?

- "For patients who are at high risk for intermittent therapy because of poor adherence or have transmitted NRTI drug resistance, a PI/r-based treatment is preferred, given the PIs high genetic barrier to resistance."

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 1, 2016; Günthard HF, et al. *JAMA*. 2014;312:410-425.

Very Low Rates of Treatment-emergent Resistance with Boosted PI Regimens

Study	n	PI	Week	Genotypes	Major PI Mutations
CASTLE[1]	440 443	ATV/RTV LPV/RTV	96	26 26	1 0
ACTG 5202[2]	463 465	ATV/RTV	96	83 57	1 0
Study 103[3]	355	ATV/RTV	144	NR	0
ARTEMIS[4]	343 346	DRV/RTV LPV/RTV	96	31 46	0 0
FLAMINGO[5]	242	DRV/RTV	48	NR	0
ACTG 5257[6]	605 601	ATV/RTV DRV/RTV	96	75 99	0 0
Single-tablet regimen DRV/c/FTC/TAF vs DRV+COBI+TVD[7]	100 50	DRV/c DRV/c	48	NR	0 0

Among 4453 patients in these trials, only 2 patients developed major PI mutations at initial VF.

1. Molina JM, et al. *Lancet.* 2008;372:646-655. 2. Daar ES, et al. *Ann Intern Med*. 2011;154:445-456. 3. Clumeck N, et al. Presented at: EACS 2013; October 16-19, 2013; Brussels, Belgium. Abstract LBPS7/2. 4. Mills A, et al. *AIDS.* 2009;23:1679-1688. 5. Clotet B, et al. *Lancet.* 2014;383:2222-2231. 6. Lennox JL, et al. *Ann Intern Med.* 2014;161:461-471. 7. Mills A, et al. Presented at: ICAAC 2014; September 5-9, 2014; Washington, DC. Abstract H-647c.

Study 130: Darunavir/Cobicistat + 2 NRTIs in Treatment-Naïve and Experienced Patients

- Darunavir/cobicistat + 2 NRTIs was well-tolerated
  - No new safety findings
- Virologic response rate 83%
  - Similar response rates, irrespective of baseline HIV RNA
  - Similar to results from the ARTEMIS trial
- Pharmacokinetic data support the once-daily administration of darunavir/cobicistat 800/150 mg

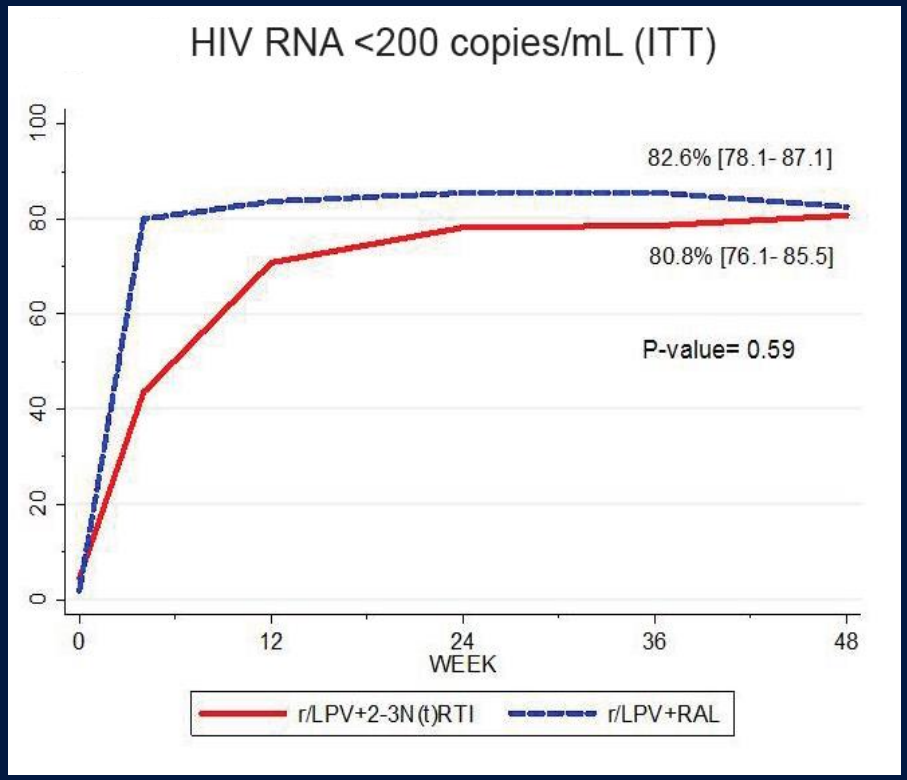
Preliminary Week-48 Outcomes (Treatment-Naïve Cohort)	
	Patients (n=295)
HIV RNA <50 copies/mL (%)	83
CD4 gain (cells/mm^3)	169
Treatment-emergent grade 3/4 (%) Adverse events Increased creatine kinase ALT/AST	 7 8 3/2
Discontinuations due to adverse events (%)	5
Most common adverse events (%) Diarrhea Nausea Upper respiratory tract infection Headache	 27 23 15 12

Tashima K, et al. *AIDS Res Ther.* 2014;11:39.

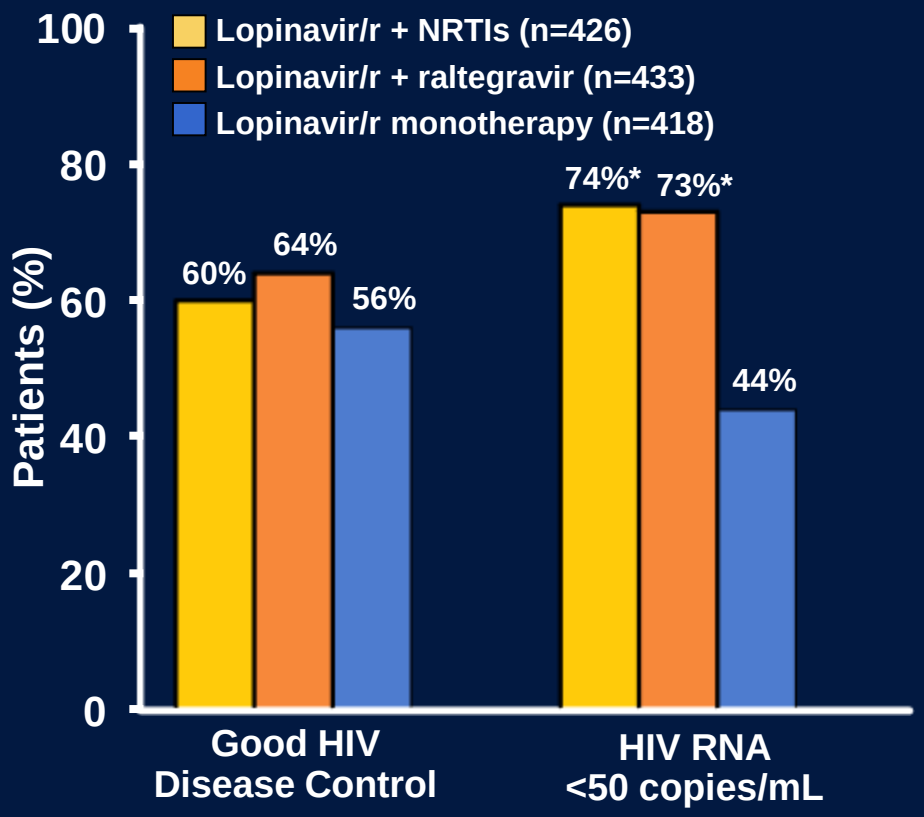
Management of First-line NNRTI Failure

Boost Protease Plus Recycled NRTI Are Enough

SECOND LINE



EARNEST

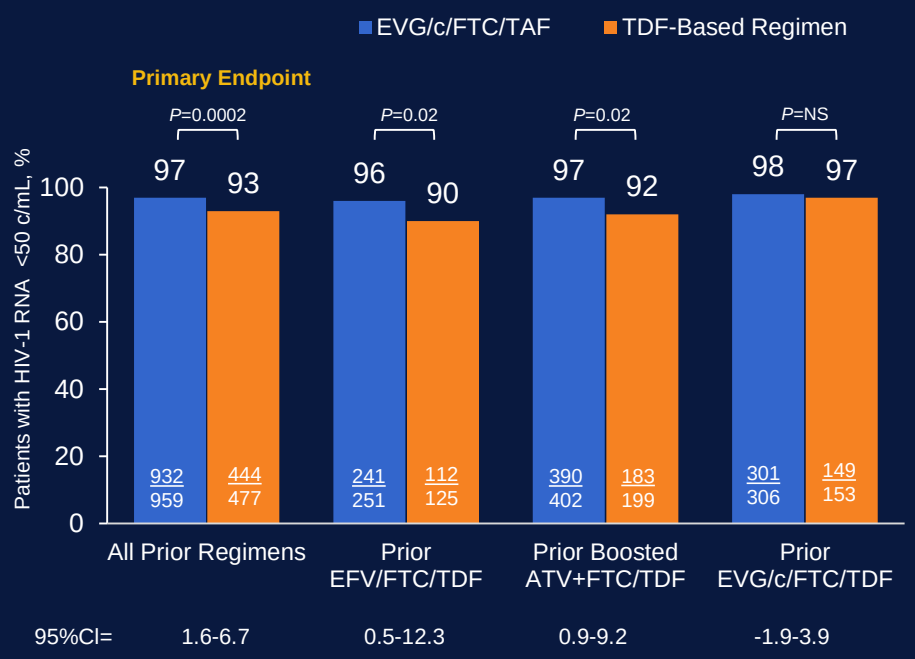


***P*<.0001 versus lopinavir/r monotherapy.**

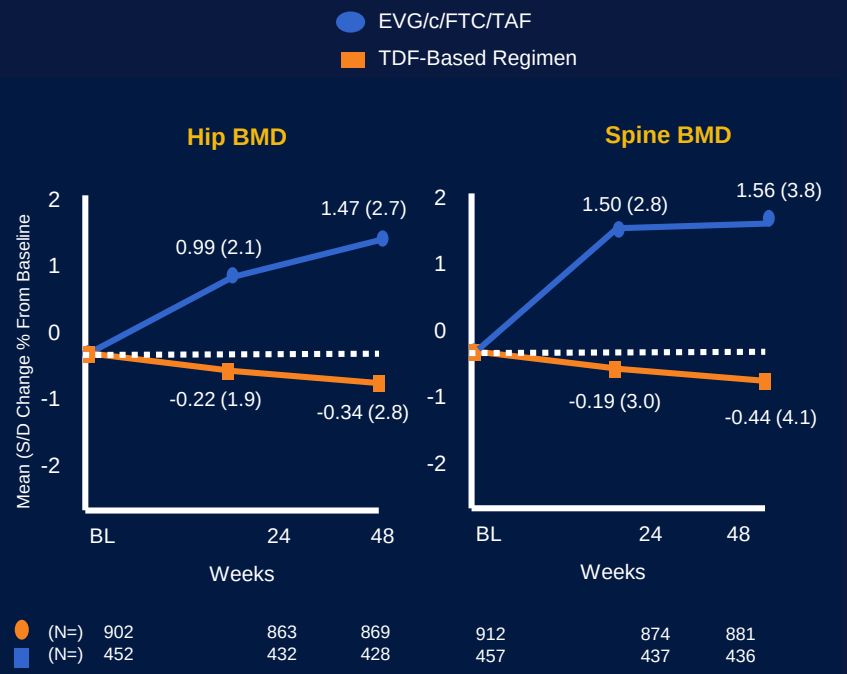
Patients with HIGHER levels of baseline resistance had better treatment responses

SECOND-LINE Study Group, et al. *Lancet.* 2013;381:2091-2099; Paton NI, et al. *N Engl J Med*. 2014; 371:234-247.

Switch to EVG/c/TAF/FTC from Several Regimens in Patients with Suppressed Plasma HIV RNA



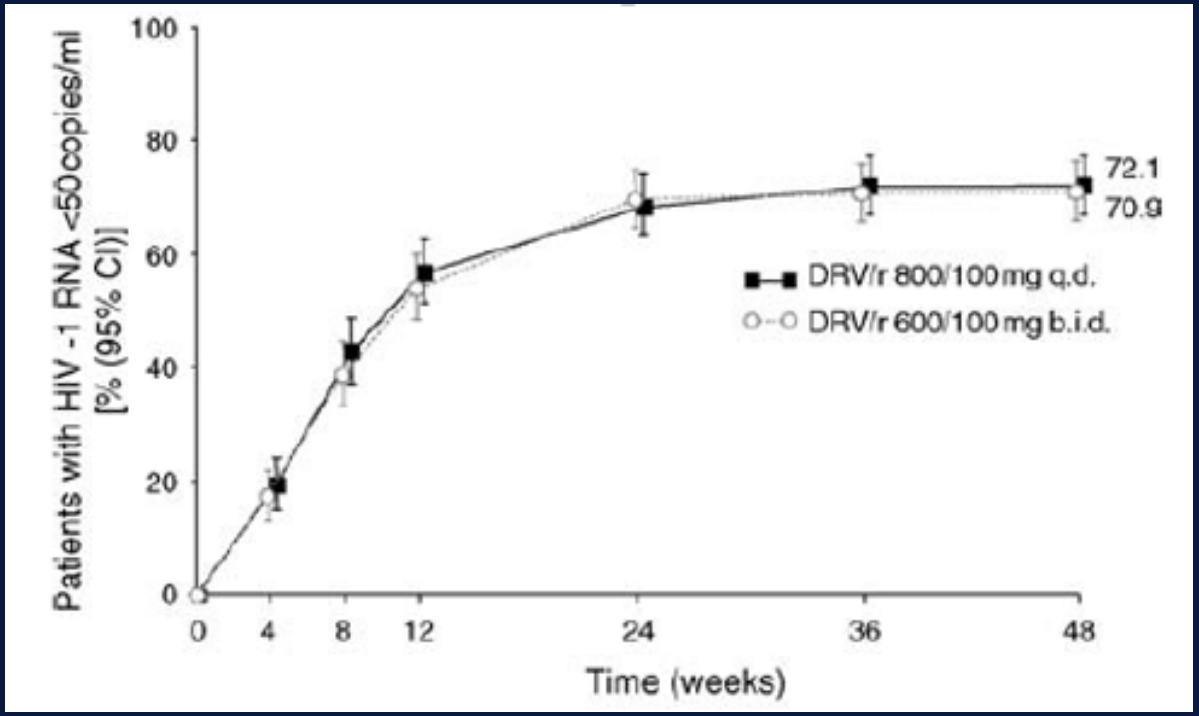
Improvements in proximal renal tubular function



P<.0001 for Week 24 and Week 48, both hip and spine

Mills A, et al. *Lancet Infect Dis.* 2016;16:43-52; Gallant JE, et al. *Lancet HIV*. 2016;3:e158-e165.

Summary of ODIN Data

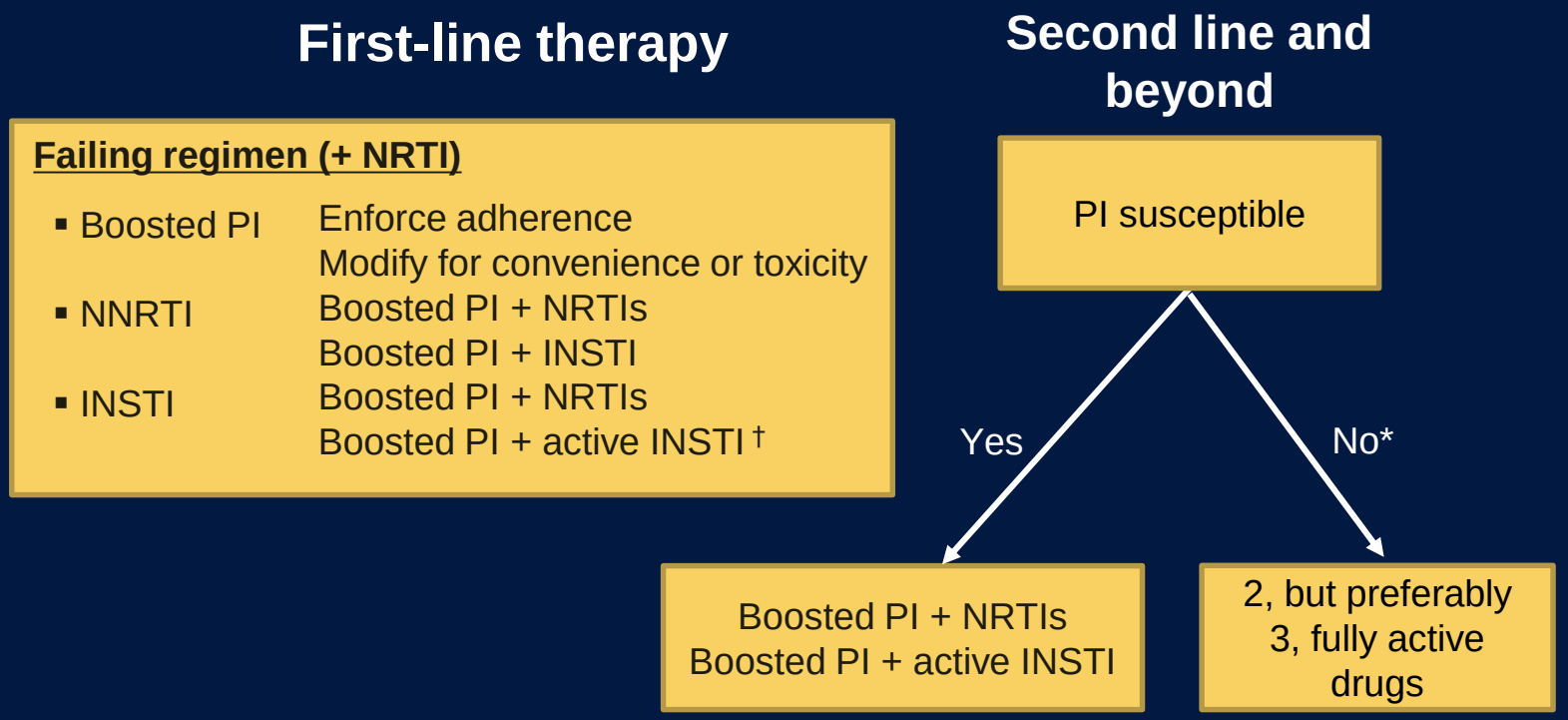


Number of PIs Previously Used	DRV/r Once-Daily		DDRV/r Twice-Daily	
0	135	111 (82.2)	137	109 (79.6)
1	74	48 (64.9)	77	49 (63.6)
≥2	85	53 (62.4)	82	52 (63.4)
M184V/I Mutation at Baseline	**DRV/r Once-Daily**		**DRV/r Twice-Daily**	
Absent	104	63 (60.6)	105	58 (55.2)
Present	190	149 (78.4)	191	152 (79.6)

ODIN = Once-daily *Darunavir* In Treatment-ExperieNced Patients.

Cahn P, et al. *AIDS.* 2011;25:929-939; Sension M, et al. *HIV Med*. 2013;14:437-444.

DHHS Guidelines: Management of ARV Failure



*Rare in patients never exposed to unboosted PI (DHHS alternative since 2003 and not recommended since 2008).
†If RAL or EVG resistance detected, DTG + boosted PI can be used if DTG susceptible.

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Updated July 2016. Accessed November 1, 2016.

Management of First-line ARV Failure DHHS Guidelines

- Failing an NNRTI plus NRTI regimen
  - Even patients with NRTI resistance can often be treated with a bPI plus NRTI or RAL.
- Failing a bPI plus NRTI regimen
  - A systematic review of multiple randomized studies of first-line bPI therapy showed that maintaining the same regimen, presumably with measure to enhance adherence is as effective as changing to new regimens.
- Failing an INSTI plus NRTI regimen
  - Patients should respond to a bPI plus NRTI.
  - A bPI plus INSTI may also be a viable option if there is no INSTI resistance.
  - If RAL or EVG resistance, DTG plus a boosted PI “can be used.”

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Updated July 2016. Accessed November 1, 2016; Günthard HF, et al. *JAMA*. 2014;312:410-425.

Causes of Virologic Failure

Patient-related Factors

- Higher baseline HIV RNA
- Lower pretreatment CD4 count
- Comorbidities that affect adherence
- Drug-resistant virus
- Prior treatment failure
- Nonadherence
- Interruption of/intermittent access to ART

ARV Regimen-related Factors

- Drug adverse effects
- Suboptimal pharmacokinetics
- Suboptimal potency
- Reduced efficacy due to patient's prior exposure to suboptimal regimens
- Food requirements
- High pill burden or dosing frequency
- Drug–drug interactions
- Prescription errors
- Cost/affordability

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Updated July 2016. Accessed November 1, 2016.

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Optimizing the HIV Care Continuum: Aligning HIV Management Strategies and Health Policy

Robert LoNigro, MD, MS

SVP and Chief Clinical Officer

Envolve PeopleCare

Austin, TX

HIV Therapy, Like Cancer Care, Requires Optimal Regimen Choice and Long-term Adherence

- Successful viral suppression depends on effective therapy of the appropriate duration
- Choosing the right treatment based on clinical circumstances
- Optimizing patient tolerance of treatment, considering adverse effects
- Optimizing treatment choice based on comorbid conditions
- Optimizing treatment choice based on social determinants

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 1, 2016; Günthard HF, et al. *JAMA*. 2014;312:410-425.

How Best to Optimize Treatment is the Most Valuable Decision To Be Made

- The cost of HIV care has shifted dramatically from treating complications to the cost of drug therapy.
- Ineffective treatment increases the cost of care by spending, not only on drug therapy but ALSO on treating complications.
- Treatment adherence to effective drug therapy ensures both cost and outcome optimization.

Payers May or May Not Have Access to HIV Treatment Expertise...Should They?

- Developing coverage policies that lead to flexibility of treatment choice is critical to success.
- Input from local subject matter experts is the best way to manage coverage policy.
- Frequent review of policy guidance keeps treatment options current.
- There is little need for ancillary clinical support when viral suppression is successful; gone are the case management strategies of the past.

Principals of Treatment Optimization

- Maximal suppression of HIV RNA reduces infectious and noninfectious morbidity and mortality and can prevent the transmission of HIV to others.
- Baseline drug resistance testing detects the presence and/or characteristics of a drug-resistant virus.
- The presence or absence of renal insufficiency, hepatitis B infection, heart disease, osteoporosis, tuberculosis, and the HLA-B*5701 allele all impact treatment choice.

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 1, 2016; Günthard HF, et al. *JAMA*. 2014;312:410-425.

Principals of Treatment Individualization

- There are currently 25 drugs in 6 classes available.
- Combination therapy with 2 nucleoside reverse transcriptase inhibitors (NRTIs), plus a third active drug from a different class, is most effective in suppressing HIV RNA, minimizing drug toxicity and reducing HIV-related morbidity and mortality.
- Patients taking medications intermittently pose a risk for resistance development, and special considerations must be made.

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 1, 2016; Günthard HF, et al. *JAMA*. 2014;312:410-425.

Considerations of Adherence Risk

Likelihood of adherence is a critical determinant in treatment choice. The following have been generally found to create a risk of lower adherence rates:

Personal barriers:

- Lack of belief in one's ability to successfully stay on treatment
- Inability to accept one's health status
- Decreased quality of life
- Worry about HIV disclosure to friends, family, neighbors, and colleagues
- Failure to develop pill-taking skills
- Illicit drug use, alcoholism
- Mental health problems

Social and economic barriers:

- Lack of social support
- Homelessness
- Poverty
- Limited or restricted access to care (insurance, ability to pay, transportation, social stigma)

Medication-related barriers:

- High pill count
- Overly complicated regimens
- The need to stay on treatment in the long term
- Disruption in supply of medications
- Adverse drug reactions

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 1, 2016;
Günthard HF, et al. *JAMA*. 2014;312:410-425.

Identifying Resistance Risk and Managing Therapy at Both the Patient and Provider Level

- Appropriate surveillance is key to ensuring optimal outcomes
  - Assessing for adverse events/side effects
  - Viral load
  - CD4 counts
- When to consider changing the medication regimen:
  - Virologic failure
  - Toxicity
  - Intolerance
  - Inconvenience or preference (eg, frequency of dosing, pill burden, or requirements for co-administration with food)

DHHS. http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed November 1, 2016; Günthard HF, et al. *JAMA*. 2014;312:410-425.

Improving the Effectiveness of Population Treatment

- Avoiding unnecessary utilization management barriers to access to care or medication therapy
- Follow pharmacy utilization data to ensure prescriptions are being filled
- Provide care coordination efforts selectively to impact the social determinants of adherence
- Ensure that every patient has access to trained and experienced HIV treatment centers/providers

Thompson MA, et al. *Ann Intern Med*. 2012;156:817-833.

Special Populations

- Pregnancy
- Treatment-experienced individuals
- Neonates
- Post-exposure prophylaxis
- Pre-exposure prophylaxis

HIV Therapy, Like Cancer Care, Requires Optimal Regimen Choice and Long-term Adherence

- Successful viral suppression depends on effective therapy for the appropriate duration
- Choose the right treatment based on clinical circumstances
- Optimize patient tolerance of treatment, considering adverse effects
- Optimize treatment choice based on comorbid conditions
- Optimize treatment choice based on social determinants
- Be vigilant for the development of treatment resistance/treatment failure

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National HIV Policies and Their Challenges

James A. Jorgenson, RPh, MS, FASHP

Chief Executive Officer

Visante Inc. & Visante Ltd.

St. Paul, MN

HIV Treatment Cascade

- HIV Infected
- Diagnosed

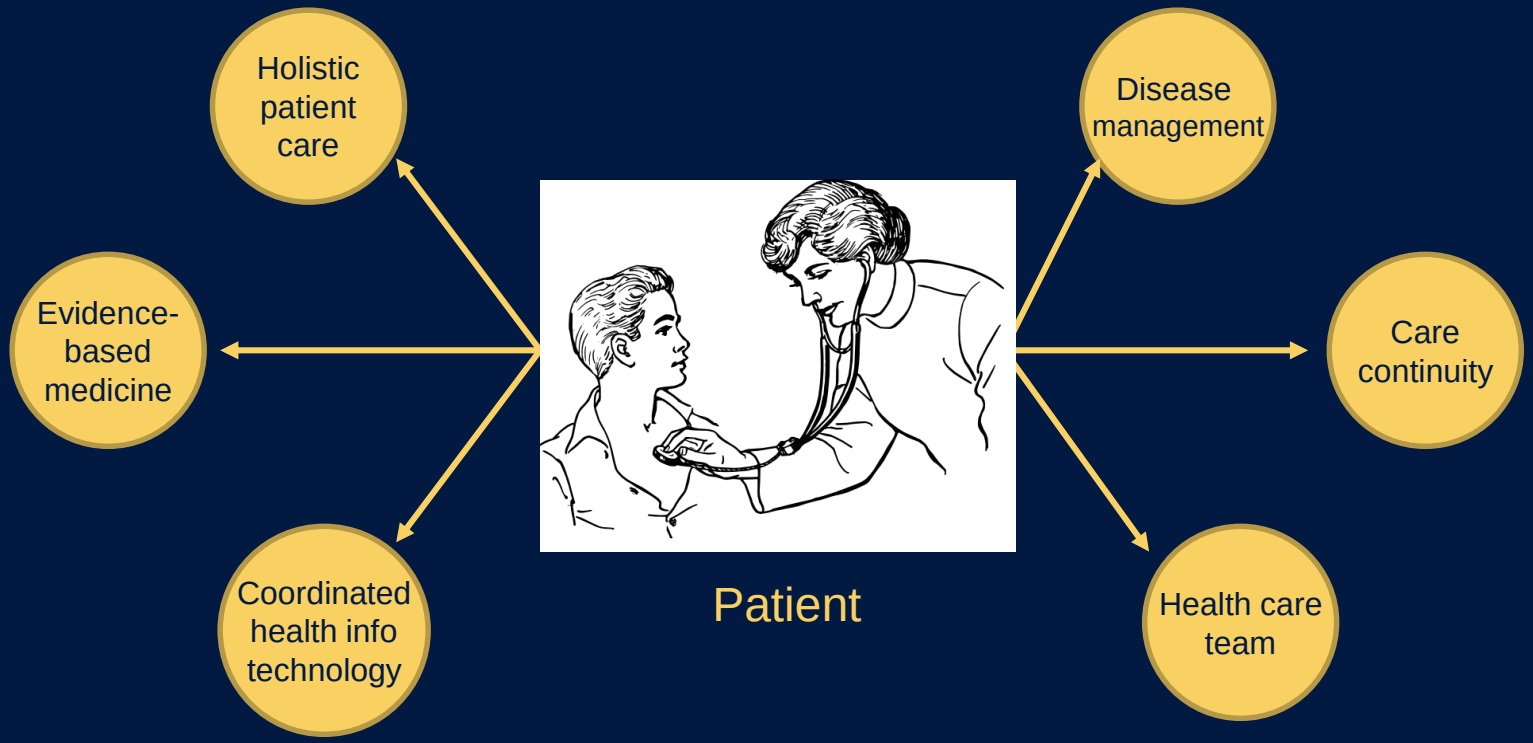
- Linked to Care
- Retained in Care

- Prescribed ART
- Virally Suppressed

Bradley H, et al. *MMWR*. 2014;63:1113-1117; Hall IH, et al. *JAMA*. 2013;173:1337-1344.

Enhanced Care Models

Patient-centered Medical Home: Physician is the “quarterback” for a comprehensive, coordinated care team, with the patient/family at the core. Pharmacist is the medication therapy expert support.



American College of Physicians. https://www.acponline.org/practice-resources/business/payment/models/pcmh/understanding/what-pcmh. Accessed September 15, 2016.

Evolutionary Health Insurance Marketplace

- In addition to rising utilization and cost trends, the Patient Protection and Affordable Care Act has created unique challenges and opportunities for payers, providers, and beneficiaries:
  - Individual coverage
  - Preexisting conditions
  - Lifetime and annual dollar limits, or “caps”

Coverage Considerations for HIV/AIDS Patients

- Cost sharing
- Continuity of care
- Utilization management
- Navigator programs
- Medical necessity and appeals
- Access to specialists and treatments

Payor Interventions to Improve Outcomes

- Formulary control
- Tiering
- Prior authorization
- Step edits/treatment guidelines
- Polypharmacy edits
- Narrow networks

Medicaid

Treatment Access and Quality

- Network access to infectious disease specialists
- Access to desired drugs/dosages
- Churning

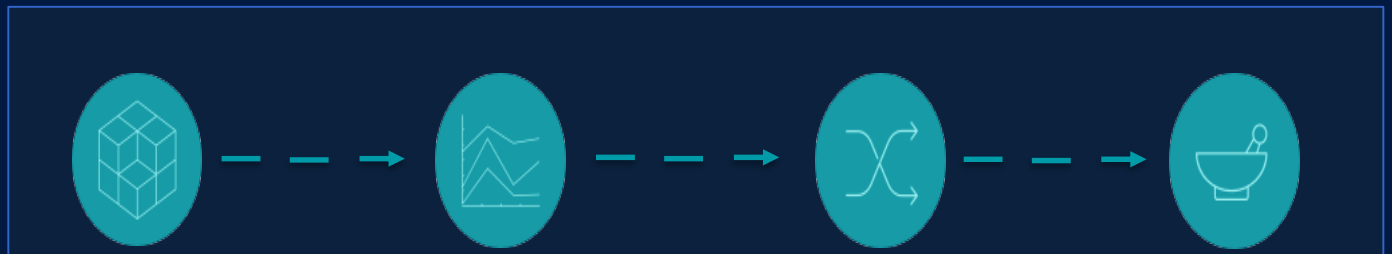
Managed Medicaid

- Medical and pharmacy carved in
- Pharmacy carved out
- Pharmacy carved in but specific disease states carved out

Expansion

- Individual state expansion
- Re-introduction of the Public Option to fill the gap

Risk Stratification Approach



DATA

Aggregate all relevant data across the community of health care providers

PREDICTIVE ANALYTICS

Algorithms that identify modifiable medication-related risk and facilitate interventions at lowest possible cost

WORKFLOW

Technology tools supporting proven medication management workflow across the community of care

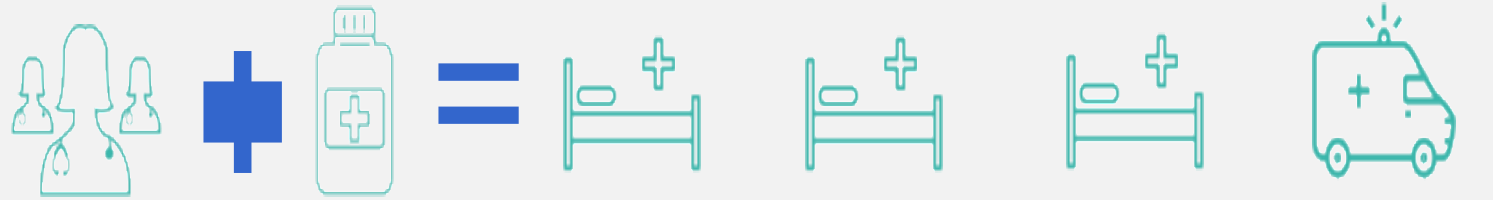
SERVICES

Centralized pharmacy personnel to provide medication management services at a fully loaded variable cost to the client

Prioritize limited resources to focus on patients who most need support to improve modifiable risk and drive higher quality and lower cost

Community Care of North Carolina

Effects of transitions of care with community medicine management



PCP Utilization	Rx Utilization	Total Hospital Admissions	Avoidable Admissions	Avoidable Readmissions	Emergency Visits
↑ 24%	↑ 20.7%	↓ 46.8%	↓ 35.4%	↓ 35.1%	↓ 16.1%

Results based on Community Care of North Carolina's demonstration project.

INDIVIDUALIZING HIV CARE
to Optimize Patient Outcomes

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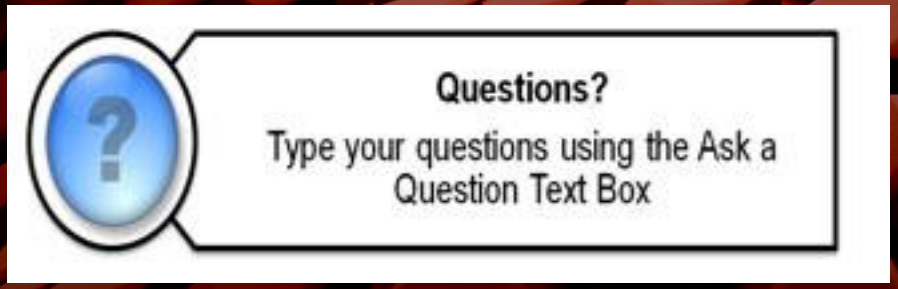
Questions and Evaluation/Certificate Instructions



Immediately following this webcast you will receive an email with a link to take the posttest to obtain your CME or CPE credits. Note the following:

1. You must correctly answer 3 out of 4 questions to pass the test.
2. Upon passing the test, you'll be prompted to fill out a brief survey about the event.
3. Once you've filled out the survey, you'll then be redirected to the certificate page to download/print your statement of credit. Please be patient while the survey loads.

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