

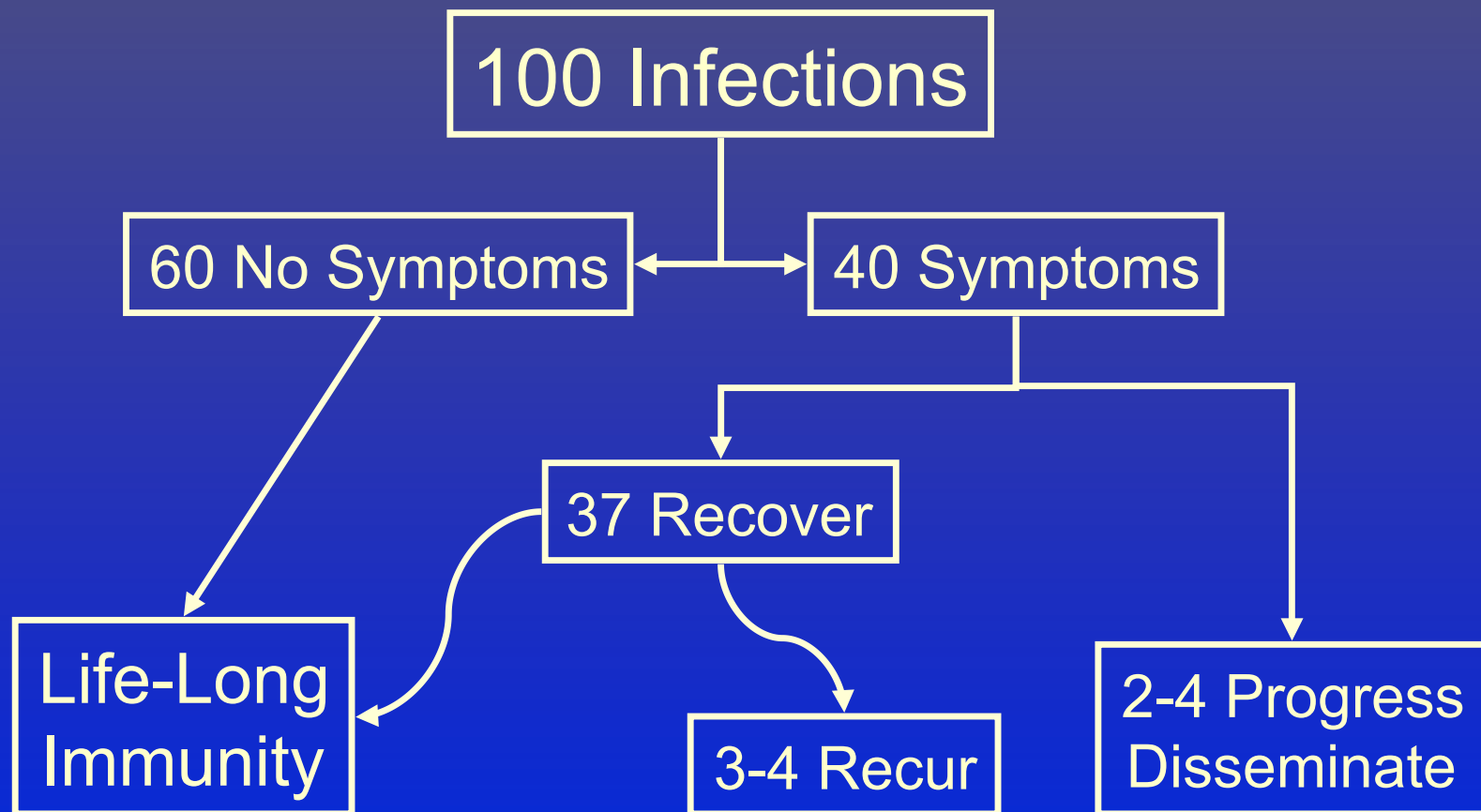
Valley Fever and What Can Be Done About It

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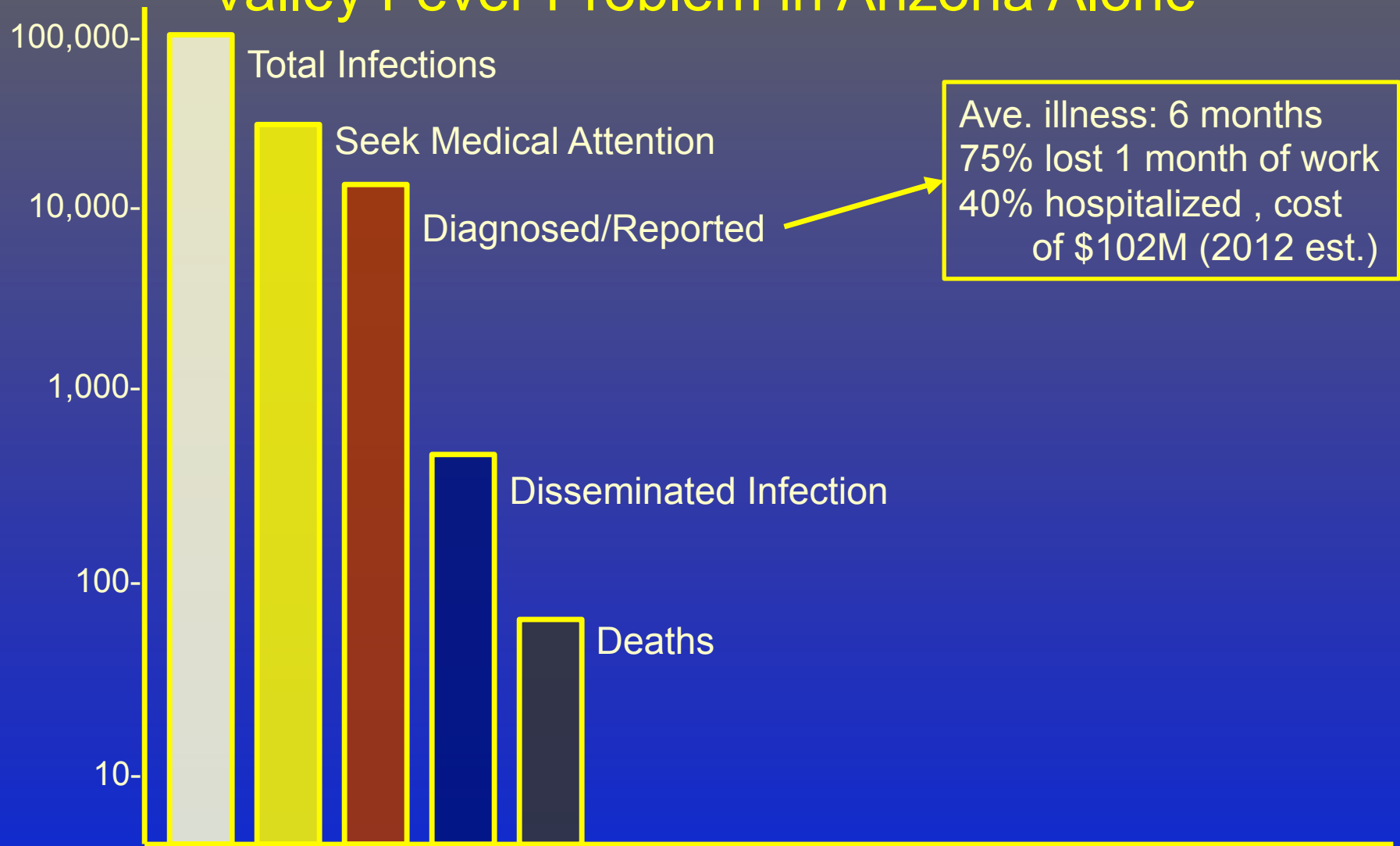
Valley Fever is a Western Hemisphere Disease



Coccidioidomycosis Spectrum of Disease



Valley Fever Problem in Arizona Alone



Complications from Valley Fever

Pulmonary

- Diffuse acute pneumonia
 - ARDS
- Peripneumonic effusion
- Nodules
- Cavities
 - Hemoptysis
 - Rupture
- Chronic fibro-cavitary pneumonia

Disseminated Infection

- Skin
- Subcutaneous abscesses
- Arthritis
- Osteomyelitis
- Meningitis

Risk Factors for Complications

Pulmonary

- Diabetes mellitus
- Cardio-pulmonary or other co-morbidities. (Evidence: “common sense”).

Disseminated Infection

- Deficient cellular immunity
- Males > Females
- Racial background
 - African-American
 - Filipino
- Adults > Children
- Pregnancy

Organizing around Valley Fever in Arizona

1978: Galgiani arrives in Arizona

1995: Galgiani goes on a sabbatical

1996: Valley Fever Center for Excellence
created.

2003: First Arizona Valley Fever
Awareness week.



11th Annual Valley Fever Awareness Week November 9th – 17th 2013

Valley Fever Alliance of Arizona Clinicians

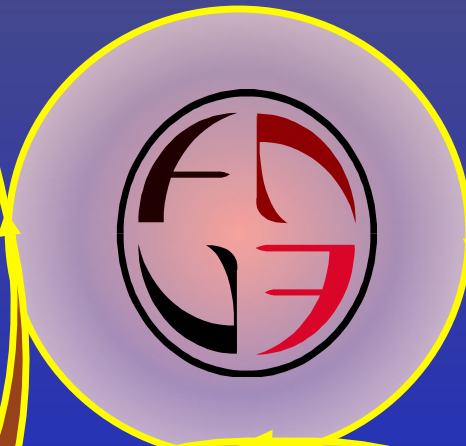
(VFAAC)

Patient
Needing
Help

Another
Subspecialist

Primary
Care
Clinician

Subspecialist

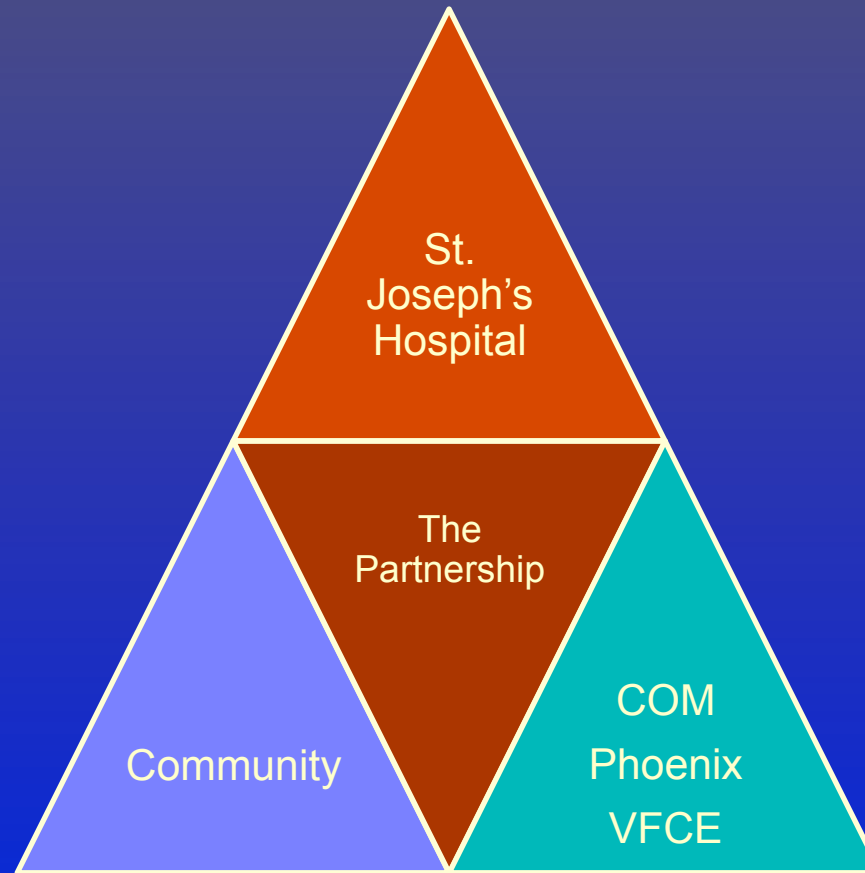




Valley Fever Center to open in Phoenix

*by Ken Alltucker - Oct. 5, 2011 12:00 AM
The Arizona Republic*

Valley Fever Center in Phoenix: June, 2012



Valley Fever Center in Phoenix First Year Summary

Source of 420 Inquires

- 61% Arizona
 - Maricopa (86%)
 - Pima/ Pinal (9%)
- 13% California
- 3% each WA, TX
- 2% each UT, CO, NY
- ≤1% each of 22 states
- Also
 - Canada, Australia, Italy,
 - Spain, Argintina

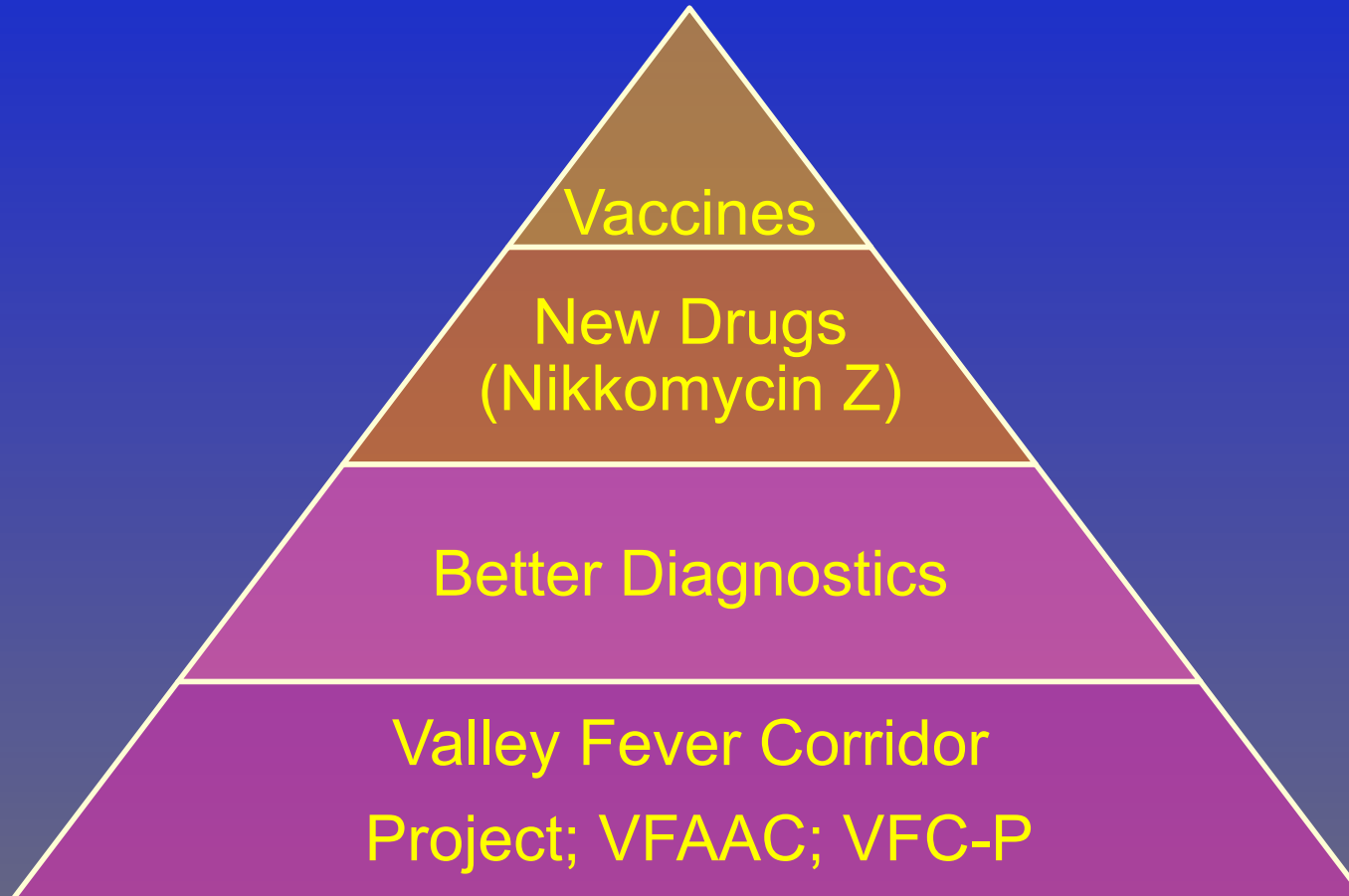
Types of Problems (132 patients)

- 25% Valley Fever
 - unlikely or inactive
- 36% “Mild” Valley Fever pneumonia
- 22% Complicated Valley Fever pneumonia
- 15% Disseminated Valley Fever

Benefits from a VFC in Phoenix

- Build on existing expertise
 - Doctors across AZ (CA and the rest of the Southwest??) can be part of the VFC/P.
 - All clinicians share a common EMR (MobileMD)
- Provide an integrated management plan for the specific needs of each patient.
- Provide case management services to ensure that planned care is provided.

Clinical Network and Research



Current Therapy for Valley Fever

Good News

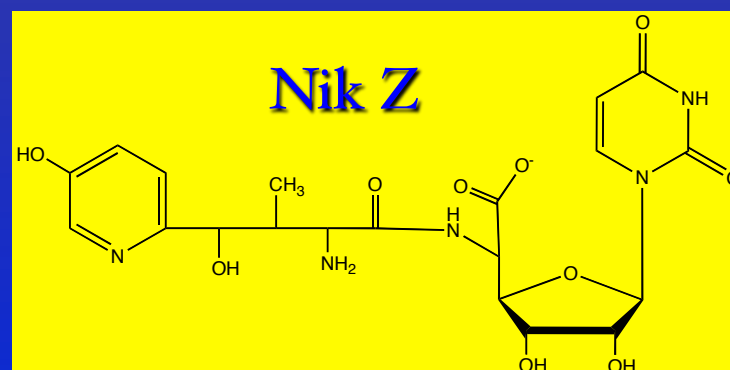
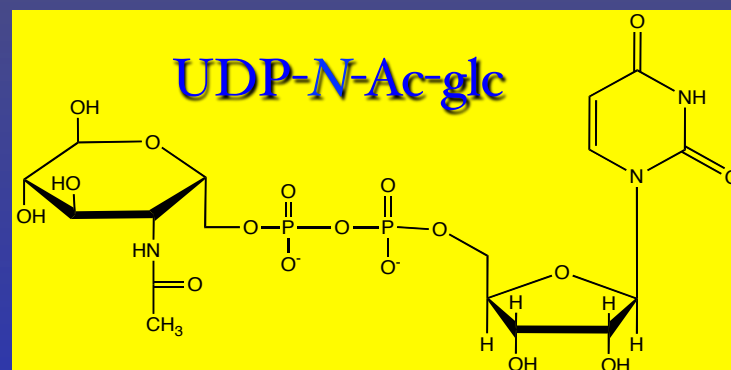
- Oral therapy with fluconazole and other azoles are safe and convenient

Bad News

- Not everyone responds to azole treatment (20-40% failure rate)
- Azole drugs do not cure infections
- Relapses when therapy stopped
 - non-CNS: ~30%
 - Meningitis: ~75%

Nikkoymcins resemble UDP-*N*-acetylglucosamine

- UDP-*N*-acetylglucosamine is a precursor to chitin
- Nikkomycin Z is a competitive inhibitor of chitin synthase



Nikkomycin Z: A Possible Cure for Valley Fever

Infection
remaining
in lungs of
mice treated
with _____

New paradigm: Complications might be prevented by curing the infection with early treatment.

No Drug
or

Nikkomycin Z

with Growth

8

1

with no Growth

0

7

Hector et al, 1990

Nikkomycin Z

- 1970s: Discovered by Bayer
 - 1980s: Cured mice with Valley Fever
 - 1990s: Development started by Shaman Pharmaceuticals
 - Company went out of business in 2000
 - Development stalled because it lacked a new pharmaceutical sponsor
- Until....
- Acquired by the University of Arizona in 2005

8 years - \$8 million

NIH

	<u>to</u>	<u>from</u>	
'06 Planning	UA	NIH	\$225K
'07 Analytic services	UA	NIH	~\$400K
'08 Pre-clinical PK/PD	VFS	NIH	\$850K
'09 Manufacturing	VFS	NIH	\$3 million

Philanthropic

JT Tai & Co Fnd. UA \$2.4 million

FDA

'07 Clinical trial UA FDA \$1.0 million

Development Restarted by U Arizona

- Phase I multidose
 - NikZ doses versus placebo:
 - 250 mg BID thru 750 mg TID for 14 days
 - Completed in 2009
 - No toxicity to date
 - Pharmacokinetics for comparison with mouse PK/PD studies for future trial design
- 2014: Make drug
- 2015: Phase II
 - 1° pneumonia syndrome
 - 2 treatment groups
 - Placebo (n-25)
 - 500 mg TID x 4 weeks
 - Complete 2017

Valley Fever Costs to Arizona

Educate Arizona patients
and doctors

\$100 thousand/year

Referral network and case
management

\$300 thousand/year

Diagnostic test
development

\$1.5 million

Nikkomycin Z development

\$40-\$60 million

Vaccine development

-- Protein vaccine: **\$40 M
just to start clinical trials**

-- Live attenuated vaccine:
Safety?????

Dogs then Humans. **\$??**

Doing nothing

**\$86 million per year just
for hospital costs**

Thank-you

Valley Fever Center for Excellence



College of Medicine

