

# VANDERBILT SPECIALTY PHARMACY

## Real World Assessment of All-Oral, Sofosbuvir-Based, Hepatitis C Therapy at an Academic Medical Center with Integrated Specialty Pharmacy Services

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### BACKGROUND

- The discovery of all orally administered, direct acting antiviral (DAA) therapies has revolutionized the treatment of hepatitis C virus (HCV).
- Clinical trials report sustained virologic response rates 12 week post therapy (SVR12) at over 90% with these newer agents as compared to SVR12 rates of less than 55% with the previous interferon-based standard of care.
- In addition to better efficacy, these new therapies also have limited side effect profiles, which, in turn, improves therapy completion rates.
- However, the strictly controlled environments of these clinical trials brings into question the external validity when considering treatment of the general population.

### PURPOSE

- To evaluate patient outcomes to all-oral, sofosbuvir (SOF)-based, HCV therapies in a real world setting and assess the impact of a clinic-integrated specialty pharmacy on therapy completion.

### METHODS

- IRB-approved, retrospective chart review.

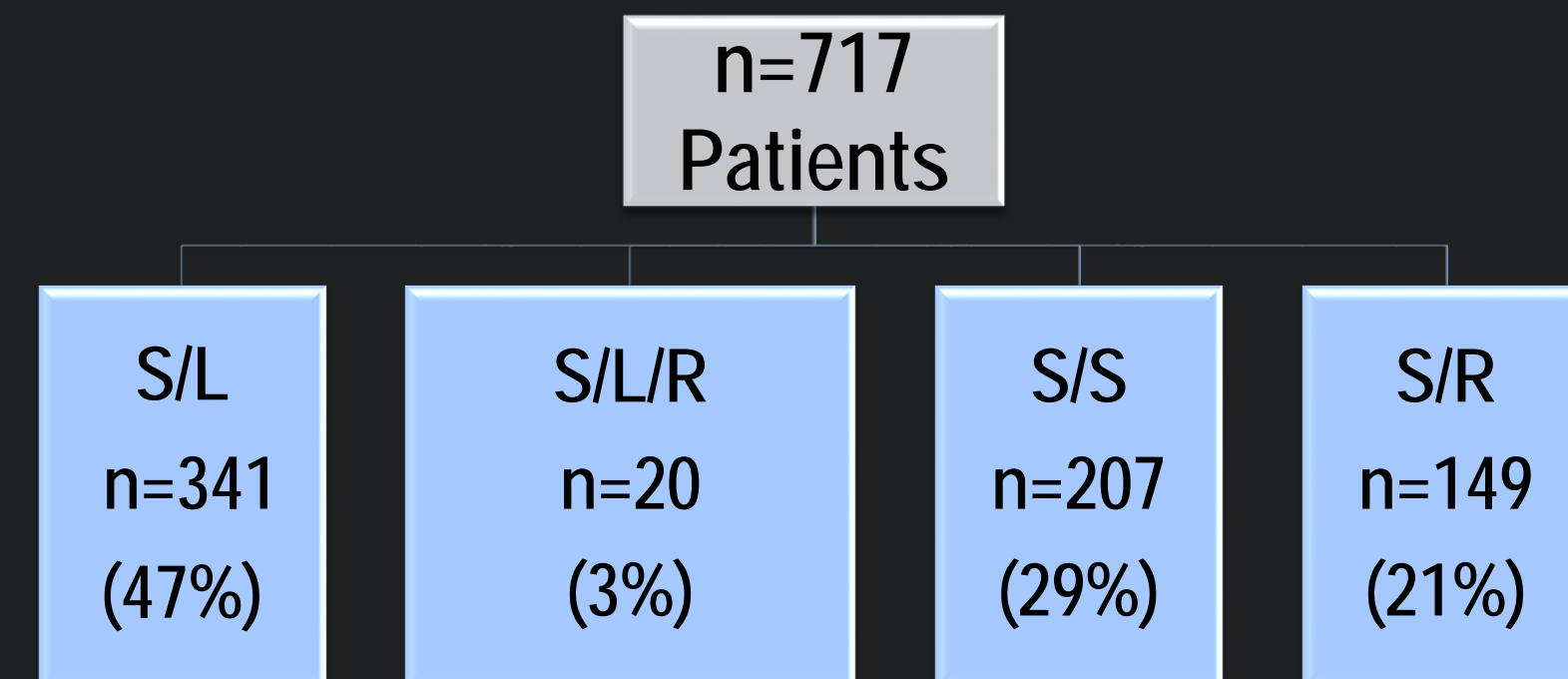
### Inclusion Criteria

- ≥18 years of age
- HCV prescription written by Vanderbilt Provider: December 1, 2013 to May 31, 2015
- Receiving HCV regimen consisting of the following:
  - sofosbuvir+ribavirin (S+R)
  - sofosbuvir+simeprevir (S+S)
  - ledipasvir/sofosbuvir (L/S)
  - Ledipasvir/sofosbuvir+ribavirin (L/S+R)

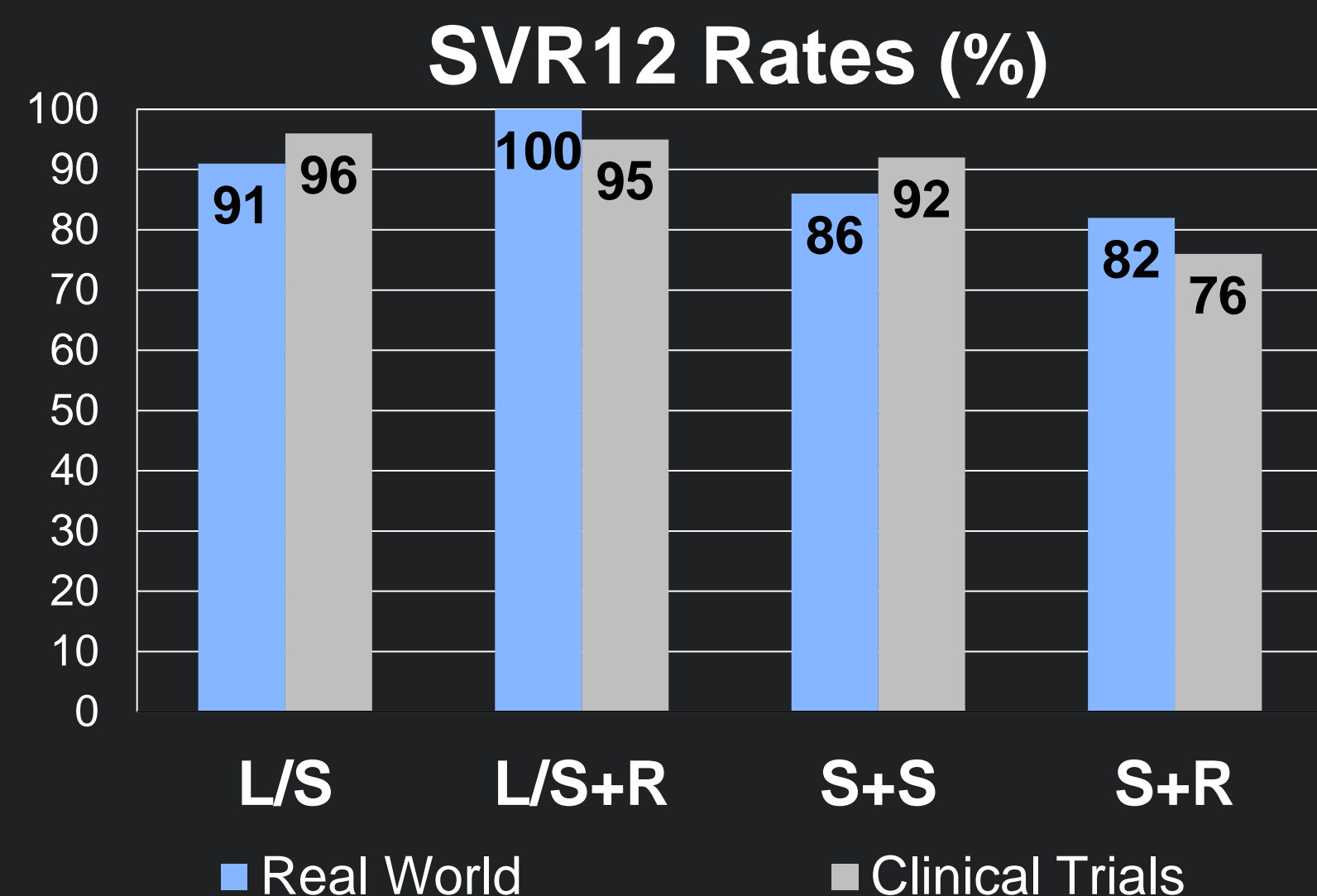
### ENDPOINTS

- SVR12 rates stratified by drug regimen
- Adverse drug events
- Discontinuation rates
- Completion rates stratified by specialty pharmacy
- Medication access via the Vanderbilt Specialty Pharmacy (VSP)
- Out-of-pocket prescription costs utilizing VSP

### RESULTS



| Demographics                          | L/S  | L/S+R | S+S  | S+R  |
|---------------------------------------|------|-------|------|------|
| Age, Yrs, mean                        | 56   | 55    | 57   | 54   |
| BMI, kg/m <sup>2</sup> , mean         | 29.1 | 30.3  | 29.7 | 29.5 |
| Male, %                               | 60   | 60    | 58   | 63   |
| Race, White %                         | 76   | 75    | 83   | 95   |
| Genotype %                            | 1/1a | 77    | 72.5 | 77   |
|                                       | 1b   | 20    | 15   | 23   |
|                                       | 2    | -     | 5    | 44.5 |
|                                       | 3    | -     | 2.5  | 34   |
|                                       | 4    | 3     | 5    | 3    |
| HCV RNA log <sub>10</sub> IU/mL, mean | 3.9  | 1.4   | 4.6  | 4.5  |
| Cirrhosis %                           | 45   | 85    | 77   | 56   |
| Decompensated %                       | 38   | 35    | 46   | 47   |
| Treatment Naive %                     | 61   | 20    | 45   | 73   |



### Adverse Events

| Adverse Events          | L/S             | L/S+R           | S+S             | S+R             | Total |
|-------------------------|-----------------|-----------------|-----------------|-----------------|-------|
| Clinical Trials %       | 75 <sup>a</sup> | 90 <sup>b</sup> | 70 <sup>c</sup> | 64 <sup>d</sup> | 76    |
| Real World %            | 59              | 80              | 69              | 82              | 67    |
| Real World Common %     |                 |                 |                 |                 |       |
| Fatigue                 | 50              | 44              | 42              | 52              | 48    |
| Headache                | 60              | 19              | 41              | 28              | 45    |
| Insomnia                | 21              | 13              | 8               | 20              | 17    |
| N/V/D                   | 40              | 19              | 37              | 42              | 39    |
| Anemia                  | -               | 38              | -               | 18              | 20    |
| Dermatologic/Pruritis   | 3               | 6               | 31              | 30              | 18    |
| Concentration/Emotional | 6               | 13              | 8               | 18              | 10    |
| Myalgias/aches          | 5               | 6               | 5               | 6               | 5     |
| Other                   | 7               | 13              | 8               | 17              | 10    |

a= ION 1, 2, 3 Trials b=SOLAR 1, 2 c= COSMOS, OPTIMIST 1, 2  
d=FISSION; VALENCE; POSITRON; FUSION; BOSON

### Completion Rates

p=0.02

Vanderbilt Specialty Pharmacy

97%

Other Specialty Pharmacy

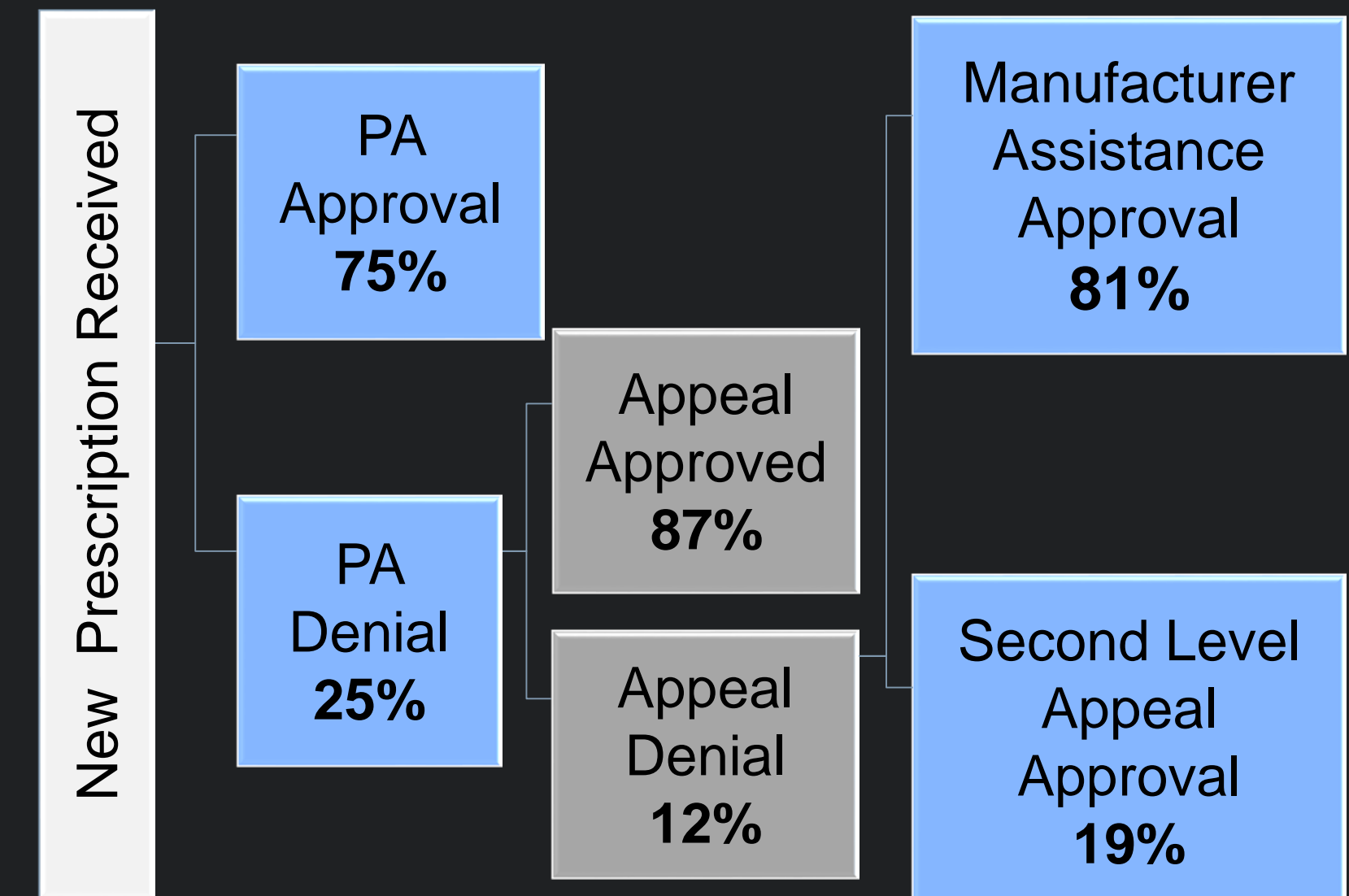
93%

### Therapy Discontinuations

| Early Discontinuations | L/S              | L/S+R            | S+S              | S+R              | Total |
|------------------------|------------------|------------------|------------------|------------------|-------|
| Clinical Trials %      | 0.4 <sup>a</sup> | 1.8 <sup>b</sup> | 1.2 <sup>c</sup> | 1.2 <sup>d</sup> | 1.1   |
| Real World %           | 2                | 5                | 2                | 12               | 4     |
| Real World Reason %    |                  |                  |                  |                  |       |
| Side Effects           | -                | -                | 50               | 61               | 39    |
| Death                  | 63               | -                | -                | -                | 16    |
| Noncompliance          | -                | -                | -                | 22               | 13    |
| Poor Response          | -                | -                | -                | 6                | 3     |
| Medication Access      | 13               | 100              | 50               | 11               | 19    |
| Other                  | 25               | -                | -                | -                | 6     |

### VSP Medication Access

Patient Access Rate=100%



### VSP Patient Prescription Costs

| Medication            | Average Out-of-Pocket Cost per Prescription* |
|-----------------------|--|
| ledipasvir/sofosbuvir | \$52.41                                      |
| simeprevir            | \$8.13                                       |
| sofosbuvir            | \$3.30                                       |
| ribavirin             | \$10.01                                      |

\*53% of patients paid \$0.00 out-of-pocket

### CONCLUSIONS

- Despite the medically diverse and largely cirrhotic patient population, the SVR12 rates of all-oral, SOF-based antiviral therapies were comparable to those demonstrated by clinical trials.
- Adverse effects were common but rarely caused early discontinuation.
- Patient utilization of the clinic-integrated Vanderbilt Specialty Pharmacy significantly increased the likelihood of completion of the full course of therapy and also provided patients with 100% access to HCV medications.
- VSP was able to service the majority (67%) of adult Vanderbilt patients treated for HCV while keeping patient pay prescription cost low.