Counting the Costs: Do we have a comprehensive strategy to fund hepatitis C treatment?

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Disclosures

Dr. Spaulding has in the past 12 months had the following relevant financial relationships with commercial interests:

- Grant Support through Emory University: Gilead
- Honorarium through third party: Merck
- Upcoming advisory board: Abbvie

Mr. von Oehsen represents state Medicaid agencies, state and local departments of corrections, 340B hospitals and clinics, 340B provider groups and pharmacies. This presentation is not to be construed or relied upon as legal advice.
OUTLINE

1. Do we know how many persons in prisons have HCV? (Spaulding)
2. How do prisons pay? (von Oehsen)
3. Pricing simplified, and creative alternatives (Spaulding)
1st QUESTION

Do we know how many persons in prisons have HCV?
Hepatitis C Prevalence in Correctional Populations

- Hepatitis C Antibody Prevalence Plateauing
- 30% of persons with HCV pass through jail or prison each year

Spaulding et al, AIDS Reviews 2017
Where is the US Hepatitis C Epidemic Now?
Putting the Pen on the Map

- Routine, universal screening, has occurred in either jails, prisons or both in at least 28 of the 50 states.
- Estimates from 2016 National Survey unless date otherwise specified; with local jail data added.
- Weighted national prevalence of HCV in prisons in 2015 was 18%.

Source:
https://www.researchgate.net/publication/321757260_Where_is_the_US_Hepatitis_C_Epidemic_Now_Putting_the_Pen_on_the_Map_as_Elimination_Efforts_Hunt_for_Remaining_Cases; Spaulding et al., ID Clinics of North America, in press.
## Estimating the Burden of Hepatitis C in Corrections

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Spaulding et al. Infectious Disease Clinics of North America. 2018  
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### Data

- Total Jail Population (N=954*)
  - HCV Rapid Tested (N=249)
  - Previously Known Positives (N=169)
  - *536 out of 954 have unknown HCV Status

### Sources

- Spaulding et al. Infectious Disease Clinics of North America. 2018
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Total Jail Population (N=954*)

HCV Tested (N=249)

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Spaulding et al. Infectious Disease Clinics of North America. 2018
Conceptual framework: HCV screening in prisons

- Most of the savings will be in the community
- At current pricing, treatment for HCV in prisons is cost-effective for society overall
- But... correctional facilities cannot afford to screen and treat all HCV infected persons
Cost-effectiveness in prisons: hepatitis C treatment

Primary challenge is cost. Who is paying?

**Prisons** bear up-front costs:
- Screening
- Counseling
- Drugs and medical care
- Connection to care after release

**Society** and individuals benefit:
- Gain life years
- Avert medical costs
- Prevent new infections

Cost-effectiveness from a societal perspective does not necessarily translate into cost-effectiveness for prisons budgets
BARRIERS TO SCREENING AND TREATING

Newly identified medical issues ➔ Greater responsibility to treat ➔ Increased medical costs

Spaulding, Chhatwal et al. Infectious Disease Clinics of North America, 2018
2nd Question

How can prisons pay?
Federal Framework: Six Federal Drug Discount Programs

- **Medicaid Drug Rebate Program (MDRP)**
  - Manufacturers are required to pay a statutorily defined rebate on all covered outpatient drugs.
  - Unit rebate amount (URA) is calculated based on the drug’s “best price” or a minimum discount off of average manufacturer price (AMP), whichever is lower, and increased by an inflationary penalty if the drug’s AMP has increased faster than the rate of inflation.
  - Virtually every state has negotiated supplemental rebates by using prior authorization and preferred drug lists.
  - MDRP rebates and supplemental rebates are exempt from “best price.”

- **340B Program**
  - Manufacturers are required to give a statutorily defined discount to safety net hospitals and federally-funded clinics that qualify as “covered entities.”
  - The 340B ceiling price is AMP minus URA.
  - Most covered entities enjoy sub-ceiling discounts on their 340B drugs.
  - 340B ceiling and sub-ceiling prices are exempt from “best price.”
Federal Framework: Six Federal Drug Discount Programs

• **Federal Ceiling Price (FCP) Program**
  • Available only to the Big Four – VA, DOD, PHS, and Coast Guard
  • Manufacturer upfront discount for brand name drugs is non-federal AMP (non-FAMP) minus 24%
  • FCP discounts extend to inpatient drug prices but not generic drugs
  • Big Four are permitted to negotiate sub-ceiling prices
  • FCP pricing is exempt from “best price”

• **Federal Supply Schedule (FSS)**
  • Prior to enactment of FCP program, virtually all federal agencies, including the Big Four, purchased their drugs through FSS
  • FSS pricing is only available to federal agencies, U.S. territories, tribal governments and others
  • In contrast to the MDRP, 340B and FCP programs, FSS prices are negotiated rather than prescribed by law
  • “Most favored customer” price is starting point in negotiations to obtain below-market prices
  • FSS pricing is exempt from “best price”
Federal Framework:
Six Federal Drug Discount Programs

• **VA Contract Program**
  • FCP program allows the Big Four to negotiate sub-ceiling prices
  • VA has been particularly successful using a national formulary and a competitive bidding process to select one or a limited number of contractors to supply drugs within specified therapeutic classes
  • Because the VA is vertically integrated, compliance with the national formulary is easier to achieve
  • VA contracted pricing is exempt from “best price”

• **Medicare Part D Program**
  • Launched in January 2006, the Medicare Part D program is an optional prescription drug benefit available to all elderly or disabled Medicare beneficiaries
  • Part D is administered through private sector commercial insurance plans – either stand-alone prescription drug plans or Medicare Part C managed care plans that include prescription drug coverage in their benefit drug packages
  • Manufacturers are required to pay rebates to close the Part D benefit’s coverage gap, commonly referred to as the “donut hole”
  • Otherwise Part D drugs are not subject to any statutorily defined discounts, rather, Part D sponsors negotiate voluntary rebates with manufacturers to reduce the cost of the drug
  • Part D pricing is exempt from “best price”
Comparison of Prices in U.S. Drug Market*

* Chart is based on rough estimates
- **AWP**: Average wholesale price. The “list” price.
- **AMP**: Average manufacturer price. The average price paid to the manufacturer by wholesaler or other direct purchaser.

### Estimated Price per Course of Treatment, DAAs for Hepatitis C

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**SOURCE**: Based on unpublished Georgia Department of Corrections data, supplied November 2017
• **AWP**: Average wholesale price. The “list” price.

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• **340B**: Maximum price that can be charged to a 340b covered entity.

**Estimated Price per Course of Treatment, DAAs for Hepatitis C**

- **AWP**: $69,773
- **AMP**: $49,657
- **340B, Medicaid Rebate**: $38,186

**SOURCE**: Based on unpublished Georgia Department of Corrections data, supplied November 2017
- **AWP**: Average wholesale price. The “list” price.
- **AMP**: Average manufacturer price. The average price paid to the manufacturer by wholesaler or other direct purchaser.
- **340B**: Maximum price that can be charged to a 340b covered entity.
- **Nominal Price**: Price that is less than 10% of AMP. Certain “safety net” providers can negotiate nominal price with manufacturers, without there being a violation of federal drug pricing laws.

SOURCE: Based on unpublished Georgia Department of Corrections data, supplied November 2017
Gap in the Marketplace: HCV Therapy Demand Curve

Spaulding, Chhatwal et al. Infectious Disease Clinics of North America, 2018
Ways of Decreasing Price

• Correctional facilities cannot afford to treat HCV infected individuals at current
  • *In a Rhode Island study, the pharmacy budget would need to be 13 times larger to accommodate the expense*

• Methods for decreasing price:
  1. Federal supply schedule--Below “Best Price”—great for the FBOP but “we” can not get it.
  2. Buying plans: Minnesota Multi-state
  3. 340B—alliance with safety net entity, such as a disproportionate share hospital
Ways of Decreasing Price: More Solutions

1. Buy patent, “licensing rights to a DAA…”
   • Recommended by recent National Academies report
3. Change 340B rules
4. Change best prices regulations
5. Nominal pricing
Ways of Decreasing Price: More Solutions

1. Buy patent, “licensing rights to a DAA…”
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5. **Nominal pricing**

Manufacturer does not need to account for prices that are “nominal” in amount,
- US law defines as drugs sold to certain non-profit “safety net providers”
- at less than 10% of the average manufacturer price (AMP).
- Federal recognition of correctional facilities as “safety net providers” would qualify them to receive nominal pricing under existing law.
- No new laws would need to be enacted to implement this strategy.
# Nominal Pricing Cost Reductions

**Table.** Cost of Treating 219 Patients with Hepatitis C under 3 Schema: AWP, 340B, Nominal Pricing (estimated at $4,000 per course of treatment), using FY18 Georgia DOC Data (Population 50,000, 12% HCV antibody positive, 9% HCV viremic)

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Nominal pricing could increase access to persons with hepatitis C, living in prisons, 97-fold compared to when systems use the 340B strategy, and 17.4-fold compared to when drugs are purchased at AWP.
Is nominal pricing a possible solution for correctional facilities to purchase DAAs?

• Requires cooperation on the part of the manufacturer, but could be beneficial to them as well
  • Prisons are an **untapped market**
  • At a nominal price of **$4,000, or even $2,000** per course of treatment, drugs could still be produced for a small fraction of sales price
  • Would not disrupt other DAA markets

• **Hurdles to nominal pricing:**
  • Finding a willing seller
  • DHHS determining that prisons can count as a “safety net provider”
  • Prisons may still need to expand budget for HCV testing and treatment
Conclusions

1. This epidemic is widespread: 30-50\% of the epidemic in persons passing through prison or jail

2. Correctional facilities are not funded well enough to treat all HCV infected persons: cost-effectiveness from a societal perspective does not necessarily translate into cost-effectiveness for prison budgets

3. Nominal pricing DAAs at less than $4,000 (but above $400) would allow corrections to afford HCV screening and treatment, leading to decreased transmission to the broader community and save money for society as a whole
QUESTIONS?