Eliminating HCV: Why Highly Effective Drugs Are Not Enough

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Agenda

• Challenge to the community
• Four areas where change or innovation is needed
• Some ideas about how we can get it done
Great progress, but more is needed

• As a community of scientists, clinicians, drug developers and advocates, we should be proud of the amazing work that has led to the creation of all oral HCV therapies that are curative in 99% of people who are treated in a short amount of time.

• However, more than 99% of the people actively infected with HCV are not able to eliminate their HCV infection due to lack of diagnosis, lack of access to treatment and lack of access to affordable drugs.
The next challenge in HCV

Let’s apply the same amount of energy and creativity to

Eliminate HCV Globally
We can’t get there from here

• The tools we have now won’t get the job done
• The challenge is to create new tools, methods, and collaborations to **Eliminate HCV Globally**

Innovative approaches must be created to overcome these four challenges

1. Improved diagnosis
2. Cure patients and eliminate new infections
3. Pay for drugs
4. Collaborate and complement each other’s work across all stakeholders
Challenge #1: Diagnosis

• The challenges are well-known
  • Expensive
  • Takes too long to get results
  • Patients are lost

• Ideally
  • Inexpensive - ≤ $5 US
  • Detect HCV RNA- 1000 IU/mL
  • Rapid - 30 min or less
  • Point of care - no central lab
  • Self-contained and off the grid

• Many companies and scientists are working on this problem
  • Most if not all require a machine to read the results
TREKtx vision: Create a hand held, point of care, inexpensive, cloud-linked HCV RNA diagnostic

- HCV RNA results uploaded to a database as a function of person, time, date, etc.
- Data accessible to treater and patient

Before Treatment

During Treatment

After End of Treatment

Results automatically sent to cloud database

Feedback to Treater

Feedback to Patient

HCV RNA data

Database

No SVR

SVR

Feedback to patient
Challenge #2:

Cure patients and eliminate new infections

- Some of the challenges
  - Patients disappear
  - Too much time and money talking to payers
  - Need a scalable method of staying in touch
  - Need to emphasize the # cured, not just the # treated
  - Missing or non compliant patients are a real problem in some settings

START
4,679 pts were treated with SOF/RBV

EOT
1861 (39.8%) were NR or missing

FU
1464 (52%) were missing

In this setting, only 29% of the patients were not lost
TREKtx vision to improve treatment

• Can’t improve what we can’t measure
  • Focus on the # cured (therapies are capable of a 95-99% SVR rate, but many people with HCV are not treated)

• Need to decrease patient loss after initiation of treatment
  • Can cloud-based non-touch-intensive methods to interact with patients facilitate cures?

• Focus on eliminating the virus in all patients by decreasing barriers to treatment
  • Treat the whole cohort of PWID and retreat reinfections

• Optimize drug combo for each situation
  • Would an all injectable combo or a short duration oral + injectable be more successful in prisons and PWID?
Primrose Patient Journey

**Pre-Treatment**
Lifestyle assessment, coaching, medical screenings, labs and procedures to maximize impact of the anti-viral therapy and optimize patient outcome.

**Treatment**
Anti-viral therapy supported by extensive monitoring and patient support with the goal being viral cure.

**Post-Treatment**
Lifestyle coaching, monitoring, and patient support for successful liver recovery from the disease.

Tarak Hassanein
Challenge #3: Paying for drugs

Challenges:

• A great need exists for low cost therapies and effective delivery strategies
• Most HCV infections occur in low/middle income and low income countries with low diagnosis and negligible treatment rates
• Many patients in high income countries (US/EU) are unable to access treatment due to high costs
• Triaging, not medically justified
• Triaging, not justified based on maximum benefit
• Real legal and budgetary constraints
• Poisoned atmosphere of “good vs bad guys”

Ideally

• We treat everyone and eliminate HCV
• All big global health funders join in
• We focus on what can be done
Different rules for different organizations

• There are three kinds of organizations
  • For Profit C Corporations
    • By law, C corporations exist solely to maximize profit for investors
  • Not-for-profit Companies
    • By law, cannot make undue profits, are supposed to contribute to the public good and get tax breaks
  • Benefit Corporation
    • A cross between a not-for-profit and a C corporation
Examples of Successful Benefit Corporations

- New Belgium Brewing
- method.
- Cabot
- Uncommon Goods
- Kickstarter
- Patagonia
- Ben & Jerry's
TREKtx is a Public Benefit Corporation (PBC)

• TREKtx’s PBC status allows us to be profitable and have the additional goals of making our drugs affordable and accessible

• We are following in the footsteps of George Merck who famously said “patients first, profits will follow”
A "good" pharma story

- In 1978, William Campbell (Merck) proposed to develop ivermectin to treat river blindness
- Merck had to decide whether or not to invest in the development of ivermectin; at the time, Merck had sales of ~$2 billion
- Merck invested millions of dollars to develop and distribute the drug and the program was later expanded to treat lymphatic filariasis
- More than 2 billion treatments have been donated to treat 250 million people annually
- Campbell and colleagues were awarded the Nobel prize in 2015 for their work
It is hard to do the “right” thing

• Merck’s decision is questioned in business schools

  • University of North Carolina at Greensboro: Given the fact that Merck is spending corporate resources to manufacture and distribute Mectizan, is the Merck Mectizan Donation Program morally justifiable? [source](http://philosophia.uncg.edu/media/phi361-metivier/readings/Case-River%20Blindness.pdf)

  • University of New South Wales in Australia: ...... In these circumstances, what should Merck do? What options would be available to it? Is it possible to rank these options according to ethical acceptability? Factors you might wish to take into consideration are that in the late ‘seventies the market was increasingly difficult for drug companies. Merck’s profits were being squeezed..... Remember also that Merck was under an obligation to look after the investments of its shareholders. Did Merck do the right thing? [source](http://www.agsm.edu.au/bobm/teaching/BE/Cases_pdf/Merckcase.pdf)
HCV global elimination requires all industry sectors

• For-profit C corporation
  • Example: Gilead is helping to eliminate HCV in Georgia and Mongolia and making affordable drugs available in 101 countries

• Not-for-profit companies
  • Example: DNDi is developing a treatment infrastructure and paradigm in Malaysia and Thailand

• Benefit corporation
  • Example: TREKtx is developing new HCV therapies that will be affordable and accessible
Challenge #4: Working together

• Challenge
  • Want an arena where competitors can work together to move the field forward in non-competitive but critical areas
  • Want a mix of clinicians, drug developers, researchers, regulators and advocates
  • Want a way for new innovative companies and labs to jump in without having to know the “secret handshake”
  • Want to have a moderator that is knowledgeable, but not one of the players
Could HCV DrAG be a model for elimination of HCV?

• The HCV Drug Development Advisory Group (DrAG) is a unique forum that brings together representatives from the US and European regulatory agencies, academia, patient advocates and the pharmaceutical industry to build consensus around drug development-related issues.
  • Diagnostics
  • Clinical trial design
  • Resistance analyses

• Organized by a central steering committee with an independent moderator (Veronica Miller, Forum for Collaborative HIV Research)
  • Working groups, open to the membership, drove policy discussions and recommendations
  • Credited with helping expedite HCV drug development

How can we work together better?

Should we use the HIV Forum to start a HCV Global Elimination Group?
(HCV GONe)