Serological response and adherence of standard dose rapid regimen catch-up hepatitis B vaccination among people who inject drugs in Manipur, India

Nalinikanta (Kanta), Rajkumar
President, CoNE

HR25 Conference
Bogota, Colombia

Community Network for Empowerment (CoNE)

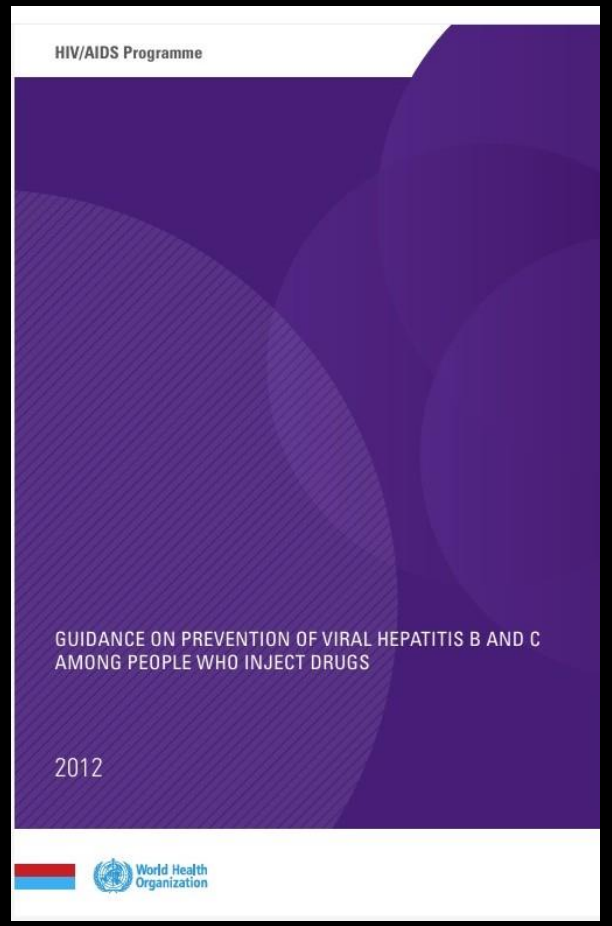
- A drug user network of 7 CBOs of people who use and inject from 6 districts of the state, established in 2011, in Manipur, India.

Range of Activities:

- Improving access to Screening, Vaccination, Diagnosis & Treatment of Hepatis B and Hepatitis C
- Improving linkages to HIV diagnosis, care and treatment services among people who use and inject drugs
- Stop human rights violation in drug treatment centre
- Improving legal awareness among PLHIV on HIV/AIDS Act, 2017

Genesis of the study

- ✓ **2012 WHO:** Recommended rapid regimen (0, 7 & 21 days) for HBV vaccination among PWID.
- ✓ Recommendation/Support high-risk groups :
  - ✓ WHO position papers, guidelines; Global Fund, US CDC etc.
- ✓ Data on efficacy of the rapid regimen has been unavailable since the initial ones three decades ago.
- ✓ National program in India do not follow this schedule.
- ✓ To understand the efficacy of HBV rapid regimen schedule in collaboration with SGPGI, TREAT Asia/amfAR & Babina Diagnostics with the financial support from Coalition PLUS.
- ✓ Compliance rate for standard schedule of 6 months among PWID is challenging.



Recommendation 1:

It is suggested to offer people who inject drugs the rapid hepatitis B vaccination regimen.

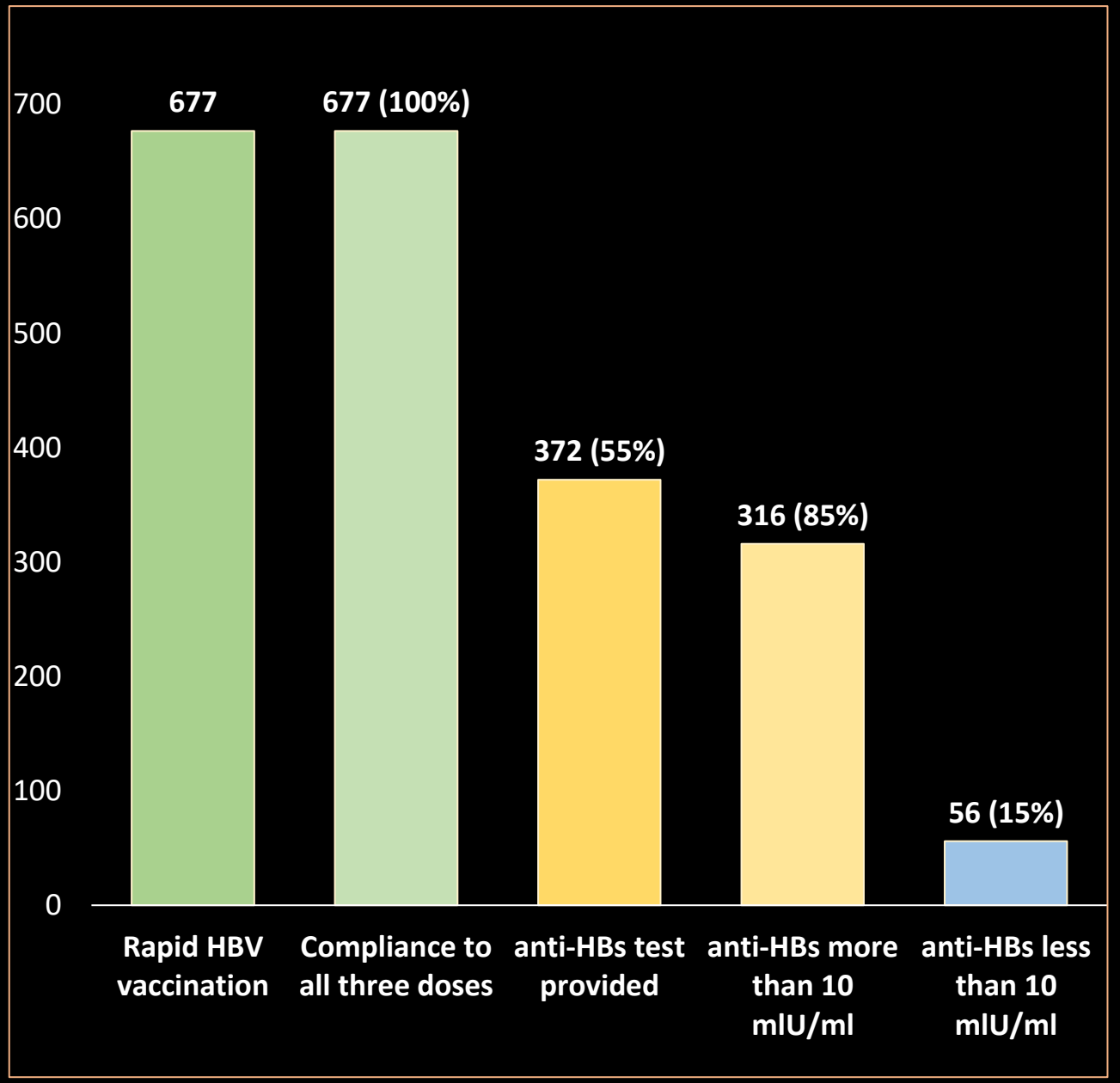
Conditional recommendation, very low-quality evidence

Method:

- 677 PWID and PLHIV received three doses HBV vaccine with rapid regimen schedule of 0, 7 & 21 days between October 2017 and August 2022.
  - Vaccine administered by peer people who use drugs at CoNE
- 372 (55%) identified for anti-HBs (Hepatitis B surface-antibody test.
- Blood samples collected from the participants after an interval of 1 to 5 years from the first dose and conducted anti-HBs test.
- Samples stored in a local diagnostic laboratory and sent in batches to a central laboratory for the anti-HBs test on a monthly basis.

Outcome:

- 667 PWID/PLHIV with rapid HBV vaccination
- 100% Compliance to the full three doses
- 372 (55%) provided anti-HBs test
- 316 (85%) Developed immunity with anti-HBs titre more than 10 mIU/ml
- 56 (15%) had anti-HBs titre below 10 mIU/mL

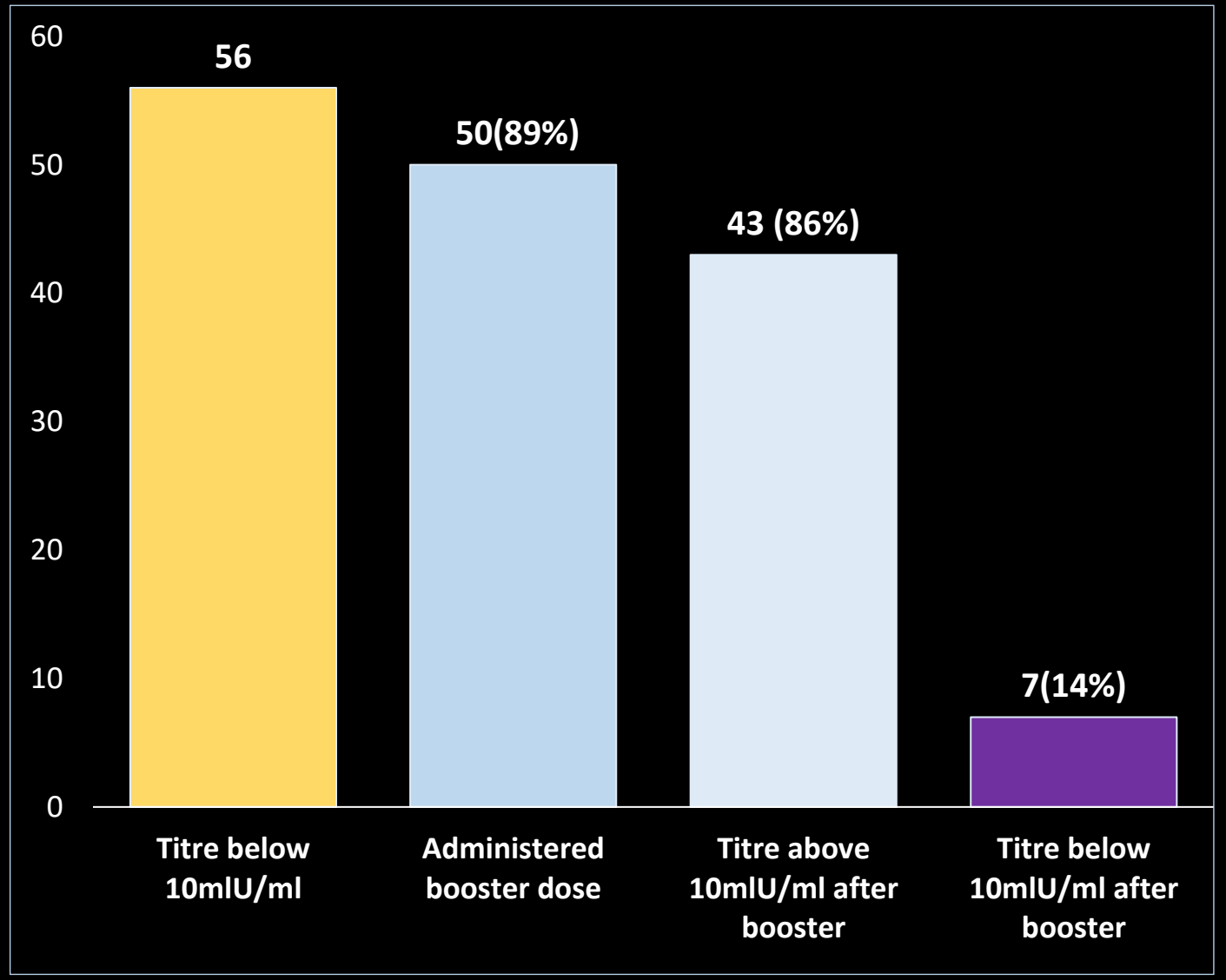


1 dose Boosters for non-responders:

- 56 non responders
- 50 (89%) provided with standard 1ml booster dose administered and anti-HBs repeated

➢ 43 (86%) achieved seroprotection with more than 10 mIU/ml after booster

➢ 7 (14%) did not respond to the booster also



Comparing rapid regimen with standard regimen

- Compared rapid regimen efficacy with standard 0,1,6 months among PWID
- **Rapid arm:**
  - 91.9% seroconversion achieved
  - 92.1% achieved seroprotection
- **Standard arm:**
  - 99.5% seroconversion achieved
  - 99.5% achieved seroprotection

Table 1 Comparison of Serological Immune Response Between the Groups Vaccinated With the Accelerated (0, 7, and 21 days) or Standard (0, 1, and 6 Months) Regimen of Hepatitis B Vaccine.

Characteristics	Accelerated regimen (n = 356)	Standard regimen (n = 211)	*P* value
Interval between the last dose of vaccine and anti-HBs titer estimation (days)	487 (422–625)	176 (105–211)	$P < 0.001$
Seroconversion achieved	91.9%	99.5%	$P < 0.001$
Seroprotection achieved in those seroconverted	92.1%	99.5%	$P < 0.001$
Anti-HBs titer	247 (57–1250)	2404 (412–12450)	$P < 0.001$

Categorical and numerical data are expressed as percentage and median (interquartile range), respectively; data between the groups are compared using nonparametric tests.

Original Article JOURNAL OF CLINICAL AND EXPERIMENTAL HEPATOLOGY

Comparison of Serological Immune Response to Hepatitis B Vaccine Following Rapid or Standard Regimen in People Who Inject Drugs

Nalinikanta Rajkumar*, Ajay K. Mishra†, Lokeshwar Khumukcham‡, Harshita Katiyar†, Dhabali Thangjam§, Rajani Singh†, Giten Khwairakpam‖, Amit Goel†

*Community Network for Empowerment (CoNE), Manipur, India, †Department of Hepatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India, ‡Jawaharlal Nehru Institute of Medical Sciences, Manipur, India, §Babina Diagnostics, Manipur, India and ‖TREAT Asia/amfAR, Bangkok, Thailand

Background & Aims: The standard regimen of hepatitis B vaccination, i.e., three doses at 0, 1, and 6 months, protects 90–95% of vaccine recipients. Compliance for three doses, administered over six months, is particularly low among people who inject drugs (PWIDs). To prevent hepatitis B virus (HBV) infection, the World Health Organization has recommend to vaccinate PWIDs with an accelerated regimen, i.e., in a 0-, 7-, and 21-day schedule. We compared the serological immune response with standard and accelerated vaccination regimens in PWIDs. *Methods:* PWIDs were vaccinated with three doses of hepatitis B vaccine as a part of routine preventive services in the past, which was not the part of our research work. Each of them had taken a conscious and informed decision to choose either the standard or accelerated regimen at the time of vaccination. For this cross-sectional observational study, anti-HBs (anti-HBs) titers were measured in vaccine recipients at ≥3 months after the administration of the third dose of vaccine. Vaccine-induced seroconversion was defined as presence of detectable anti-HBs titer, and seroprotection was defined as anti-HBs titer measuring ≥10 mIU/mL. Numerical and categorical data are expressed as median (interquartile range) and percentage (proportion), respectively; groups were compared using nonparametric tests. *Results:* The study included 567 PWIDs (all men; age: 29 [24–38] years) vaccinated with either the accelerated (n = 356; 62.8%) or standard (n = 211; 37.2%) regimen. Participants' ages were comparable ($P = 0.99$) in accelerated (29 [24–38.5] years) and standard (29 [24–37] years) groups. The interval between the last dose of vaccine and anti-HBs titer estimation was significantly longer in the accelerated group (487 [422–625]) than in the standard group (176 [105–211] days) ($P < 0.001$). A higher proportion achieved seroconversion in the standard group than in the accelerated group (99.5% vs 91.9%; $P < 0.001$). Among those who achieved seroconversion, a larger proportion in the standard group were seroprotected than in the accelerated group (99.5% vs. 92.1%; $P < 0.001$). Anti-HBs titer was significantly higher in the standard group (2404 [412–12450] mIU/mL) than in the accelerated group (247 [57–1250] mIU/mL) ($P < 0.001$). *Conclusions:* Accelerated regimen of hepatitis B vaccination is well accepted among PWIDs and provides seroprotection to a large proportion of vaccine recipients, though the vaccine-induced antibody titers remain relatively lower. For high-risk groups such as PWIDs and other mobile population groups, an accelerated vaccination regimen may be a reasonable alternative to the standard vaccination schedule. (J Clin Exp Hepatol 2025;15:102501)

https://doi.org/10.1016/j.jceh.2025.102501

Conclusion:

- 21 days rapid-regimen HBV vaccination is feasible among PWID & PLHIV.
- 100% compliance to the vaccine schedule
- 85% with anti-HBs sero protection without booster dose
- Significant response with single booster dose (86% of non-responder) achieving seroprotection
- Rapid regimen seroprotection comparable to standard 6 month regimen
- Effective public health strategy for PWID, PLHIV, high-risk and highly mobile groups to control new infections

Acknowledgements:

- All colleagues at CoNE and PWID and PLHIV participants
- TREAT Asia/amfAR, Bangkok
- SGPGI, Lucknow, India
- Babina Diagnostics, Manipur, India
- South and South-East Asia (SASEA) platform