

PPE et PPrE : le plein potentiel du personnel

Raphael Belleuf
Pharmacien

*27^e Symposium sur les aspects cliniques de l'infection par le VIH
27 novembre 2020*



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Conflits d'intérêts

Aucun conflit d'intérêt a déclarer



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Objectifs

- Connaître le rôle actuel et à venir du pharmacien communautaire dans la prise en charge des patients recevant une PPrE
- Comprendre la place du pharmacien dans la prise en charge des patients sous PPE dans le cadre du projet de loi 31 sur la pharmacie
- Connaître les récents travaux de recherche clinique sur la PPE



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Pharmacien et PPrE

4

- Suivi Prep partagé médecin/pharmacien
 - Voir plus de patients
 - Rejoindre plus de candidats a la Prep
 - Prescription dépistage VIH
 - FSC : fonction rénale, transaminases
- Améliorer accessibilité a la Prep
- Quelles responsabilités pour le pharmacien?
- Contexte COVID-19 : accessibilité diminuée au médecin

Pharmacien et PPE : projet de loi 31 sur la pharmacie

Projet de loi voté à l'Assemblée en 2019
Dans l'attente des règlements d'application

Principes directeurs

Favoriser l'intérêt du patient en améliorant l'accessibilité à la PPE
Initier la PPE le plus tôt possible
Favoriser la collaboration interprofessionnelle
Engager la responsabilité professionnelle du pharmacien



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Pharmacien et PPE : projet de loi 31 sur la pharmacie

Ce que contient le projet de loi:

Possibilité d'initier une PPE dans les 72h suivant une exposition accidentelle au VIH

Prescrire les antirétroviraux dont l'utilisation est approuvée pour cette indication

Fournir la médication pour une durée de 3j

Référer le patient a un médecin – 72h



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Pharmacien et PPE : projet de loi 31 sur la pharmacie

L'intervention du pharmacien

Fournir un espace de confidentialité et d'écoute
Accorder le temps nécessaire à la consultation
S'abstenir de tout jugement

Evaluation du risque encouru par le patient

Type de contact

A quel moment?

Eligible PPE?

Adopter une plus grande flexibilité



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Pharmacien et PPE : projet de loi 31 sur la pharmacie

L'intervention du pharmacien

Choisir un régime médicamenteux adapté

Analyser les interactions éventuelles avec le reste de la médication le cas échéant

Prodiguer les conseils appropriés et fournir feuillet d'information

Diriger le patient vers une structure à même de le recevoir dans les délais impartis



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Pharmacien et PPE : projet de loi 31 sur la pharmacie

Obstacles attendus

Situation d'urgence

Exigence de connaissance sur la PPE pour tous les pharmaciens
Choix de la thérapie
Counseling

Détenir en tout temps des médicaments nécessaires et onéreux en stock

Information du public : rejoindre une clientèle hors des grands centres urbains. **Coût!**

Quels médecins – cliniques dans la région? **LISTE**



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Pharmacist Attitudes toward Dispensing Post-Exposure Prophylaxis, New York City, 2014

Amanda K. Reid^{1,2}, Julie E. Myers^{2,3}, Vibhuti Arya^{2,4}, Zoe Edelstein²

¹Mailman School of Public Health, Columbia University, Department of Epidemiology, New York,
²New York City Department of Health and Mental Hygiene, Bureau of HIV/AIDS Prevention and Control, New York,
³Columbia University Medical Center, Department of Medicine, Division of Infectious Diseases, New York
⁴St. John's University, College of Pharmacy and Health Sciences, New York

Contact: Amanda Reid
 areid2@health.nyc.gov
 561-289-9125

Abstract #86

Background

- Over 117,000 people living in NYC have been diagnosed with HIV/AIDS, and nearly 3,000 were newly diagnosed in 2013¹
- HIV post-exposure prophylaxis (PEP) is the use of anti-retroviral medication to prevent acquisition of HIV infection among HIV-negative persons who have a specific high-risk exposure to HIV
- PEP must be administered within 72 hours
- In some clinical settings (e.g., ER or STD clinic), PEP "starter-packs" (first 1-3 days of meds) are dispensed as the first step before referral to primary care
- Pharmacists are currently unable to dispense starter-packs in New York State, but would be able to with the expansion of Collaborative Drug Therapy Management (CDTM) laws
- Expanding CDTM to community settings may allow pharmacists to dispense PEP more quickly than physician-ordered prescription

Objective

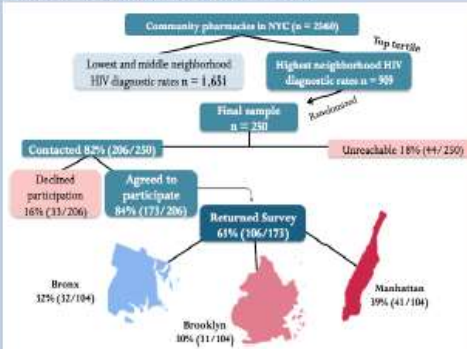
We explored New York City (NYC) pharmacists' willingness to dispense PEP starter-packs via CDTM.

Methods

- Study design**
- Cross-sectional survey administered by the NYC Department of Health and Mental Hygiene (DOHMH), June - August 2014
- Study population**
- Survey respondents were NYC supervising pharmacists practicing in community pharmacies in neighborhoods with the highest tertile of HIV diagnosis rates in 2012²
- Data collection**
- Respondents recruited via phone; offered web- or fax-based survey
 - Participants received up to 3 reminder calls to complete survey
 - Offered a \$15 coffee shop gift card for completing the survey
- Survey instrument**
- 39 questions, including:
 - Pharmacist/Pharmacy demographics
 - PEP and CDTM knowledge
 - Willingness to dispense PEP starter-packs via CDTM
 - Perceived benefits and challenges of this practice
- Data analysis**
- χ^2 and Fisher exact test for crude analyses
 - Multivariable logistic regression to model willingness
 - Statistical significance defined as $P < 0.05$

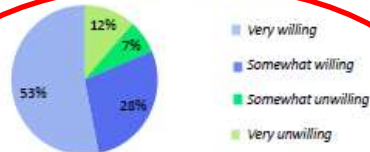
Results

Figure 1. Study sample and pharmacy location



Key Result: Overall response rate was 42% (n/N = 106/250)

Figure 2. Pharmacist willingness to dispense PEP via CDTM (N = 106)



Key result: 81% of pharmacists reported being willing to dispense PEP via CDTM (Somewhat or very willing, collapsed for further analyses)

Table 1. Pharmacist knowledge and willingness to dispense PEP via CDTM (N = 106)

Characteristic	n/N	%	n/N	% Willing
Prior PEP knowledge				
Yes	76/102	75	57/70	81
No	26/102	25	20/24	83
Prior CDTM knowledge				
Yes	26/101	26	23/26	89
No	75/101	74	54/69	78

Key result: Willingness was not significantly different ($P > 0.05$) across characteristics surrounding pharmacists' prior knowledge

Table 2. Pharmacist and pharmacy characteristics and willingness to dispense PEP via CDTM, NYC, 2014 (N = 106)

Characteristic	n/N	%	n/N	% Willing
Total	106/106	100	78/96	81
Pharmacist Characteristics				
Sex				
Male	79/100	79	62/76	82
Female	21/100	21	15/19	79
Pharmacy school graduation year (yr)				
GY < 1985	35/106	33	21/29	72
1985 ≤ GY < 1999	38/106	36	31/36	86
GY ≥ 2000	33/106	31	26/31	84
Hours per week dispensing prescriptions				
< 36	11/99	11	7/11	64
36+	88/99	89	69/83	82
Pharmacy Characteristics				
Pharmacy type				
Chain	17/105	16	12/14	86
Independently Owned	88/105	84	64/77	83
Borough				
Bronx	32/104	32	23/30	77
Brooklyn	31/104	30	23/28	82
Manhattan	41/104	39	31/36	84
Separate private space				
Yes	93/104	89	69/84	82
No	11/104	11	8/11	73
Number of prescriptions filled on a typical day ^a				
Less than 100	18/98	18	13/16	81
100 - 199	49/98	50	31/43	72
200 - 399	24/98	25	20/22	91
400+	7/98	7	7/7	100

^aPercentages were rounded to the nearest whole number and thus may not add up to 100%

Key result: Willingness was not significantly different ($P > 0.05$) across pharmacist and pharmacy characteristics examined

Table 3. Benefits and challenges of dispensing PEP via CDTM (N = 106)

Benefits/Challenges	Select any N = 106	Select one N = 88
Benefits		
Helps customers in an emergency situation	73%	53%
Addresses a need in our community	53%	36%
Skills of pharmacists increased	42%	7%
None	6%	3%
Challenges		
Pharmacists' discomfort dispensing without physician Rx	26%	31%
Lack of separate private space in the pharmacy	25%	23%
Pharmacists are too busy	19%	23%
Pharmacists' discomfort with screening questions	13%	13%
Other*	6%	3%
None	0%	7%

*Other reported challenges: concerns surrounding payment/reimbursement, patient comfort level, and authenticity of the screening questions

Limitations

- Self-reporting/social desirability bias: respondents may be inclined to report having knowledge, after informative survey questions or because the survey was administered by NYC DOHMH
- Generalizability of our findings to pharmacists outside NYC or in other NYC neighborhoods may be limited

Discussion

- Pharmacists practicing in high burden NYC neighborhoods were willing to dispense PEP starter-packs through an expanded version of CDTM
- Willingness was high across all-subgroups examined; highest among those who fill 200-399 or 400+ prescriptions per day (91% and 100%, respectively) and lowest among those who spend less than 36 hours per week dispensing prescriptions (64%).
- To put PEP via CDTM into practice in NYC, the following barriers would need to be addressed:
 - CDTM would have to be made a permanent law and expanded to retail pharmacy settings
 - Effective education of pharmacists about current PEP and CDTM practices
 - Operational issues in the pharmacy (e.g., private space and time constraints)

References

- NYCDOHMH. HIV Surveillance Annual Report, 2013. <http://www.nyc.gov/html/doh/downloads/pdf/dires/surveillance-report-dec-2013.pdf>. Accessed Jun 27 2014.
- NYCDOHMH. New York City HIV/AIDS Surveillance Statistics 2012-2014.

Acknowledgements

We would like to acknowledge the study participants and our research assistants Hina Ghani, Lina Lin, Bhumi Pandhi, Valentina Ramirez.

Travaux de recherche récents sur la PPE

Enjeux

Raccourcir la durée de traitement
Assurer une protection équivalente aux schémas de 28 jours

Résultats préliminaires chez l'animal. Non approuvé par Santé Canada.

Problématique éthique de réaliser des études randomisées pour cette indication



PNMVH

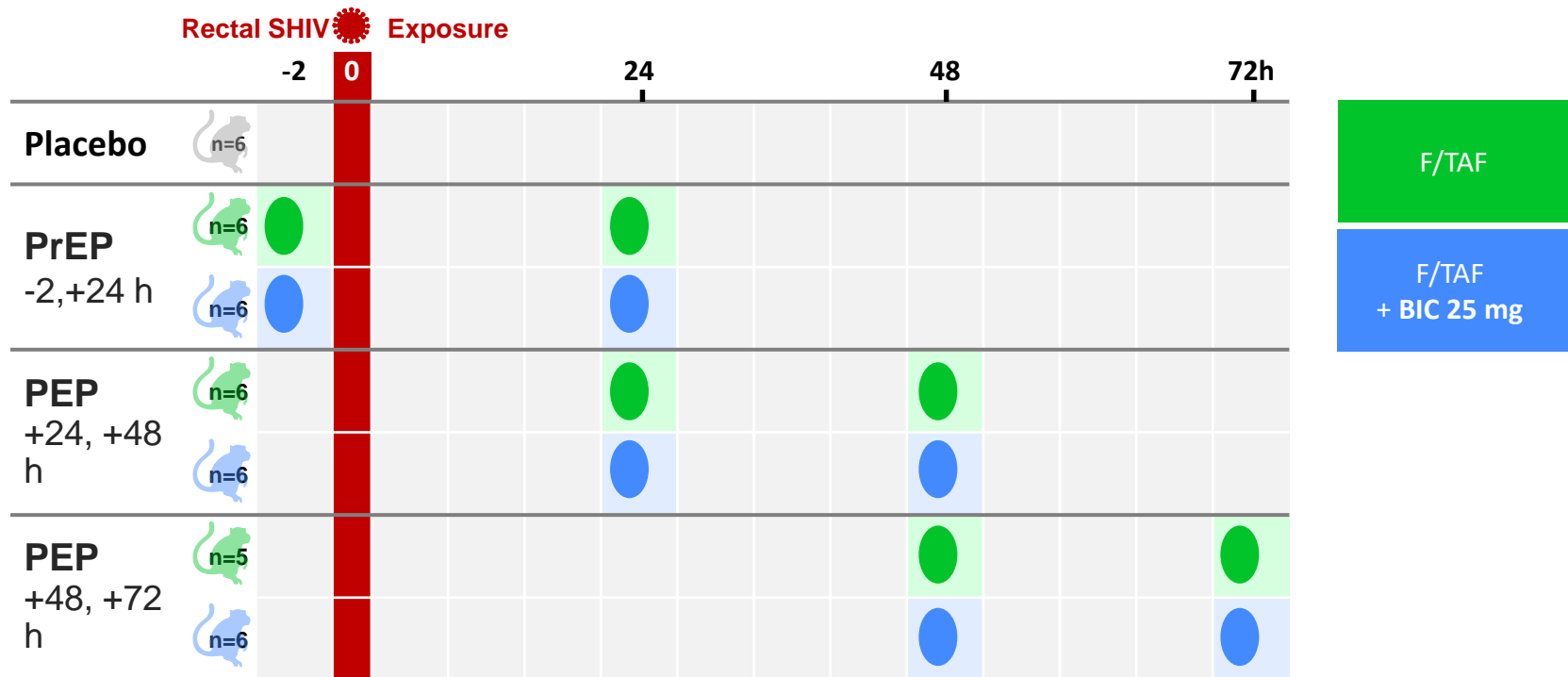
PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES

Expérimentations chez l'animal. Non approuvé chez l'Homme

F/TAF + BIC Pre- and Post-Exposure Prophylaxis in Rhesus Macaques

Study 1 Design

- Objective: assess protective efficacy of F/TAF ± 25 mg BIC



The use of F/TAF + BIC for event driven Pxp (pre/pre-post/post) of HIV and the BIC 25 mg and 100 mg doses are investigational and have not been determined to be safe or effective in humans for PrEP
 Bekerman E, et al. CROI 2020, Boston, MA. Oral 3079

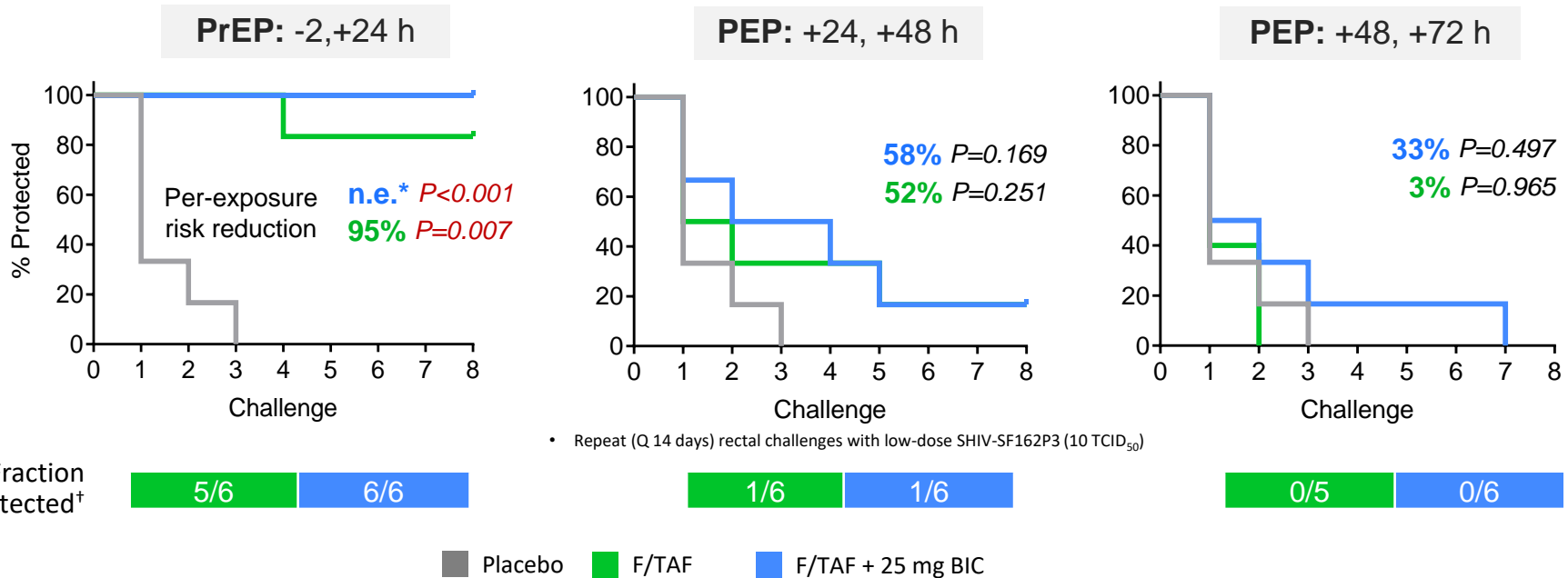


Expérimentations chez l'animal. Non approuvé chez l'Homme

F/TAF + BIC Pre- and Post-Exposure Prophylaxis in Rhesus Macaques



Study 1: Results of F/TAF vs F/TAF + BIC 25mg in Event-Driven PrEP and PEP



Significant[‡] protection was seen with F/TAF ± 25 mg BIC -2, +24 h relative to exposure

The use of F/TAF + BIC for event driven Pxp (pre/pre-post/post) of HIV and the BIC 25 mg and 100 mg doses are investigational and have not been determined to be safe or effective in humans for PrEP

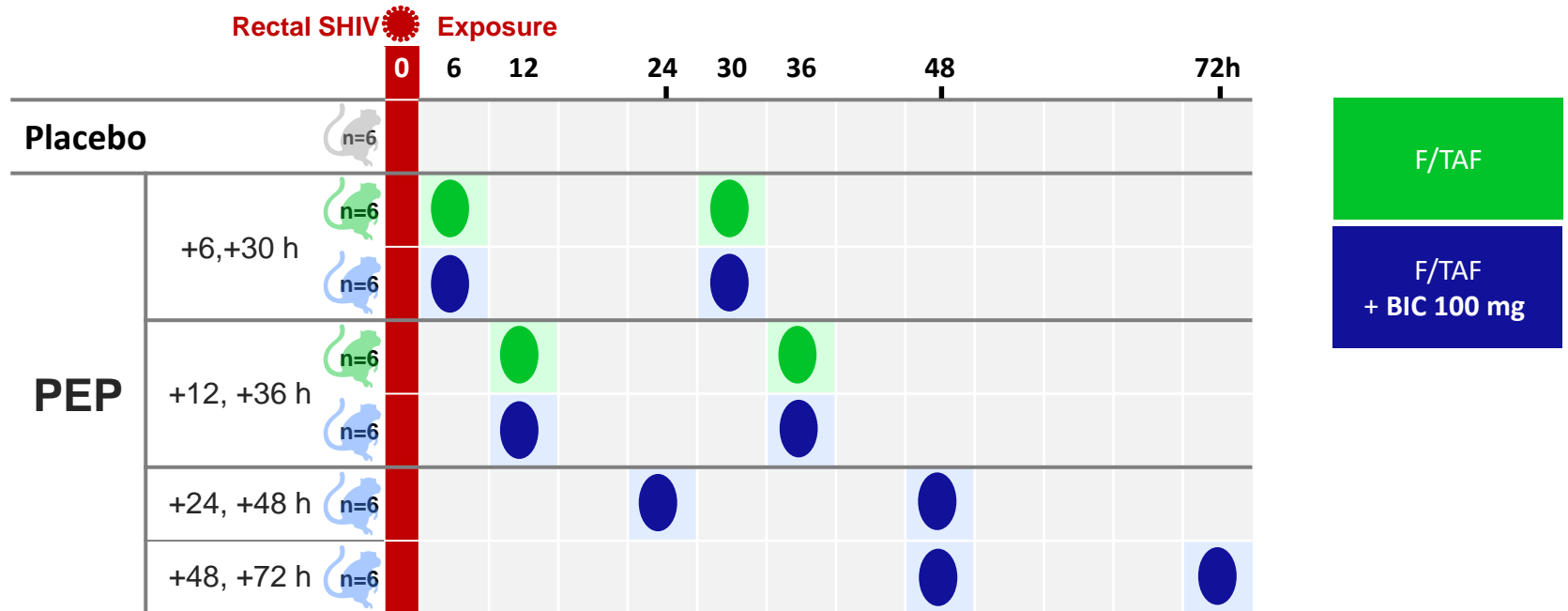
*Not estimable due to no infection events. [†]6/6 placebo-treated macaques infected. [‡]Cox proportional hazard model.
Bekerman E, et al. CROI 2020, Boston, MA. Oral 3079

Expérimentations chez l'animal. Non approuvé chez l'Homme

F/TAF + BIC Post-Exposure Prophylaxis in Rhesus Macaques

Study 2 Design

- Follow-up study objectives:
 - Test PEP regimen initiation earlier than 24 h post-exposure
 - Assess protective efficacy of a **higher bicitegravir dose (100 mg)** in combination with F/TAF



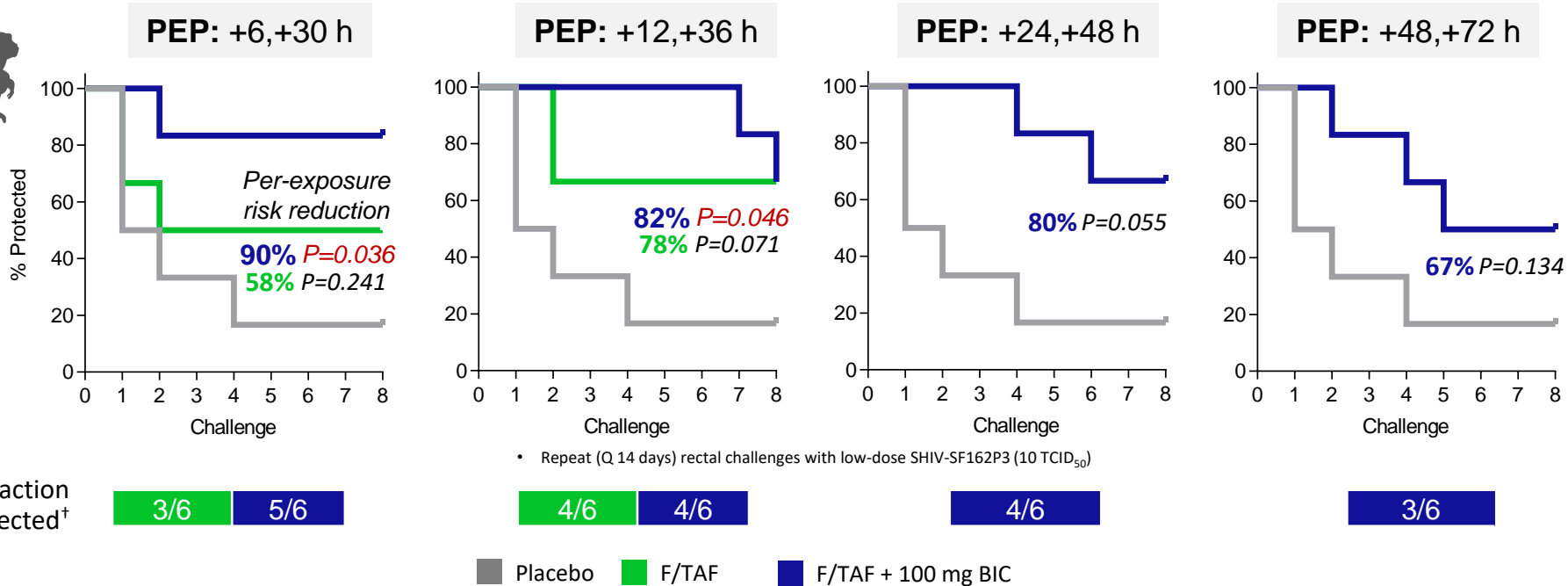
The use of F/TAF + BIC for event driven Pxp (pre/pre-post/post) of HIV and the BIC 25 mg and 100 mg doses are investigational and have not been determined to be safe or effective in humans for PrEP
 Bekerman E, et al. CROI 2020, Boston, MA. Oral 3079

Expérimentations chez l'animal. Non approuvé chez l'Homme

F/TAF + BIC Post-Exposure Prophylaxis in Rhesus Macaques



Study 2: Efficacy of F/TAF vs F/TAF + 100 mg BIC in Event-Driven PEP



Significant[†] protection was seen with F/TAF + BIC 100 mg up to 12 hours post-exposure

The use of F/TAF + BIC for event driven Pxp (pre/pre-post/post) of HIV and the BIC 25 mg and 100 mg doses are investigational and have not been determined to be safe or effective in humans for PrEP
[†]5/6 placebo-treated macaque infected. [†]Cox proportional hazard model.
 Bekerman E. et al, CROI 2020, Boston, MA. Oral 3079

Expérimentations chez l'animal. Non approuvé chez l'Homme

16

†

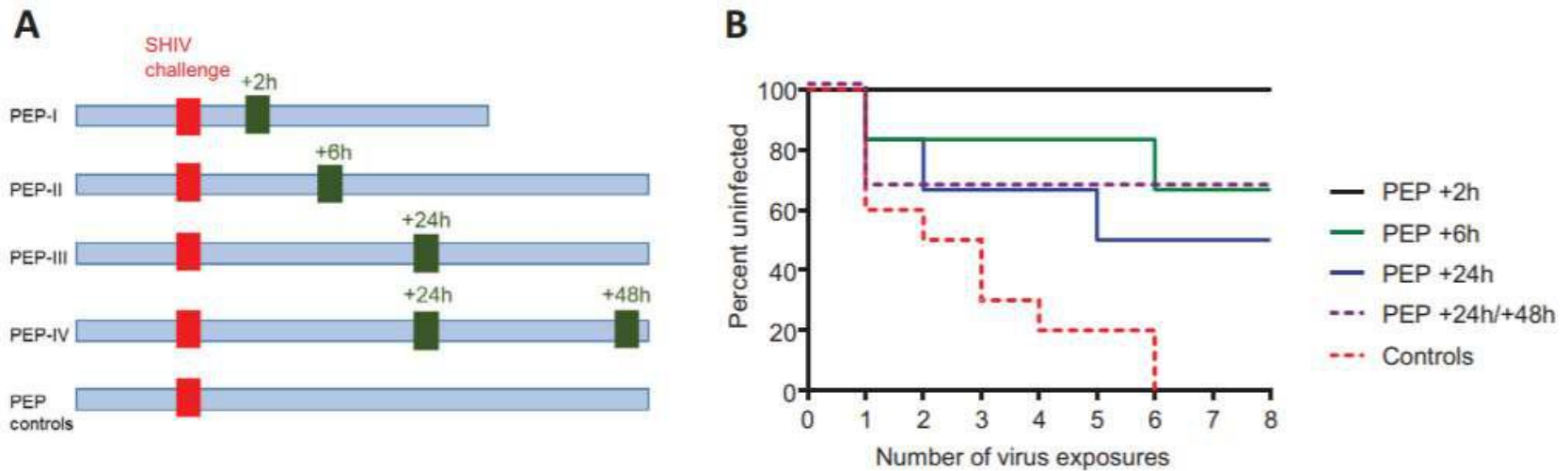


Fig 4. Efficacy of single oral doses of FTC, TAF and boosted EVG as PEP in macaques. A) Study design. B) Macaques received FTC, TAF and boosted EVG orally by gavage at the indicated time points relative to the time of rectal SHIV exposure. Survival curve shows the cumulative percentage of uninfected macaques as a function of the number of rectal SHIV exposures. Time to infection was delayed in animals receiving single-dose PEP 2h or 6h after exposure ($p < 0.001$ and $p = 0.011$, respectively). Time to infection was also delayed in animals receiving two PEP doses at 24 and 48h after exposure but not with a single +24h dose ($p = 0.013$ and $p = 0.057$, respectively).

Merci de votre attention



PNMVH

PROGRAMME NATIONAL
DE MENTORAT SUR LE VIH
ET LES HÉPATITES