A ‘ONE-STOP-SHOP’ INTERVENTION INTEGRATING POINT-OF-CARE HCV RNA TESTING TO ENHANCE HEPATITIS C TESTING AND TREATMENT UPTAKE AMONG NEW RECEPTIONS TO PRISON: THE PIVOT STUDY

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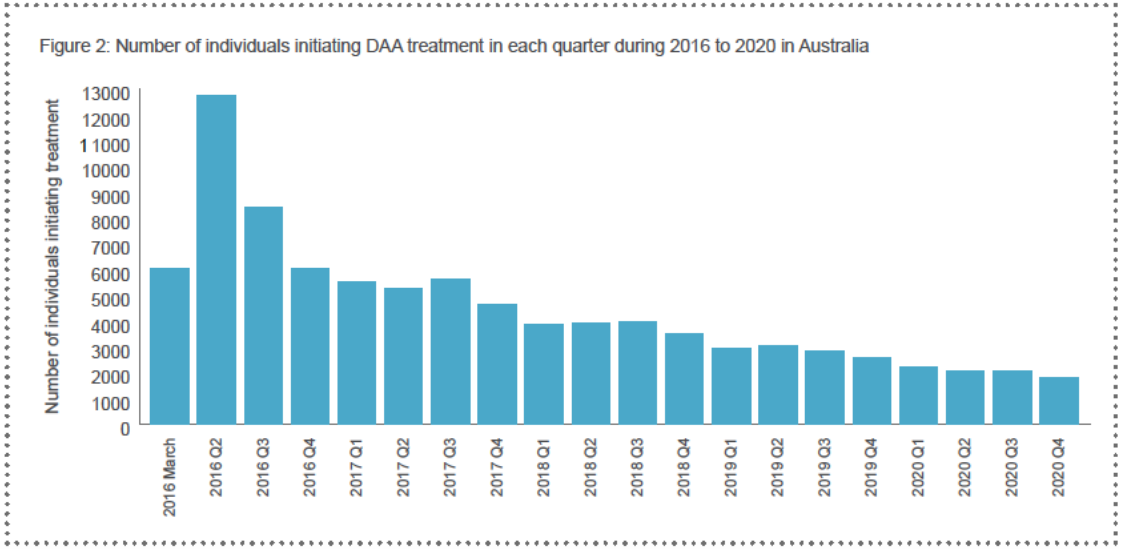
Disclosure statement

No personal remuneration received from pharma

Importance of prisons in elimination

1

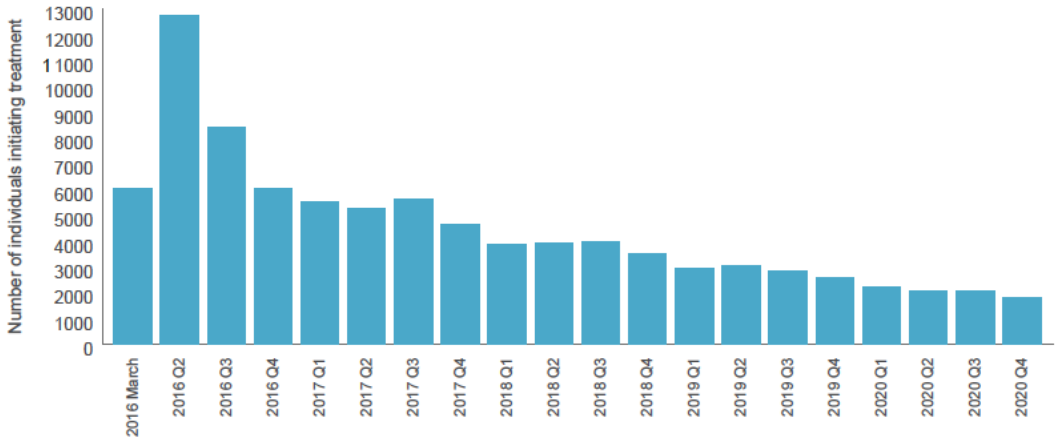


- Australia no longer on track to achieve WHO 2030 targets
- Prisons key venues for HCV elimination

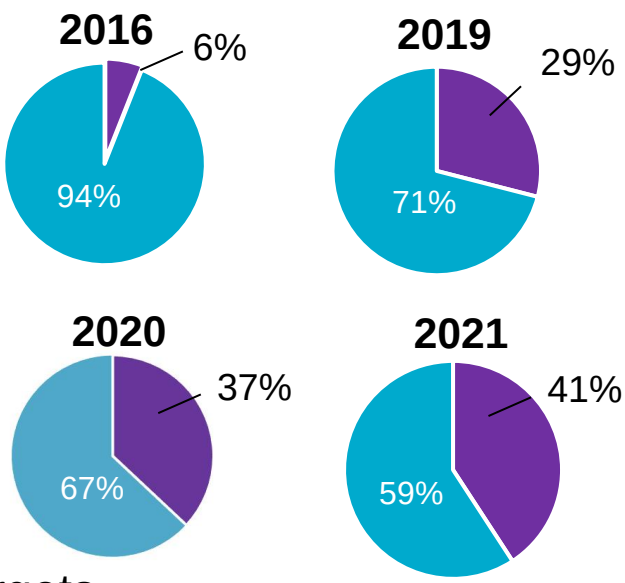
Hajarizadeh Kirby Institute 2021; Papaluca MJA 2019; PTER Kirby & Burnet Institutes 2020, 2021, 2022

Importance of prisons in elimination

Figure 2: Number of individuals initiating DAA treatment in each quarter during 2016 to 2020 in Australia



[1] **Prison-based treatment initiations** [2, 3]



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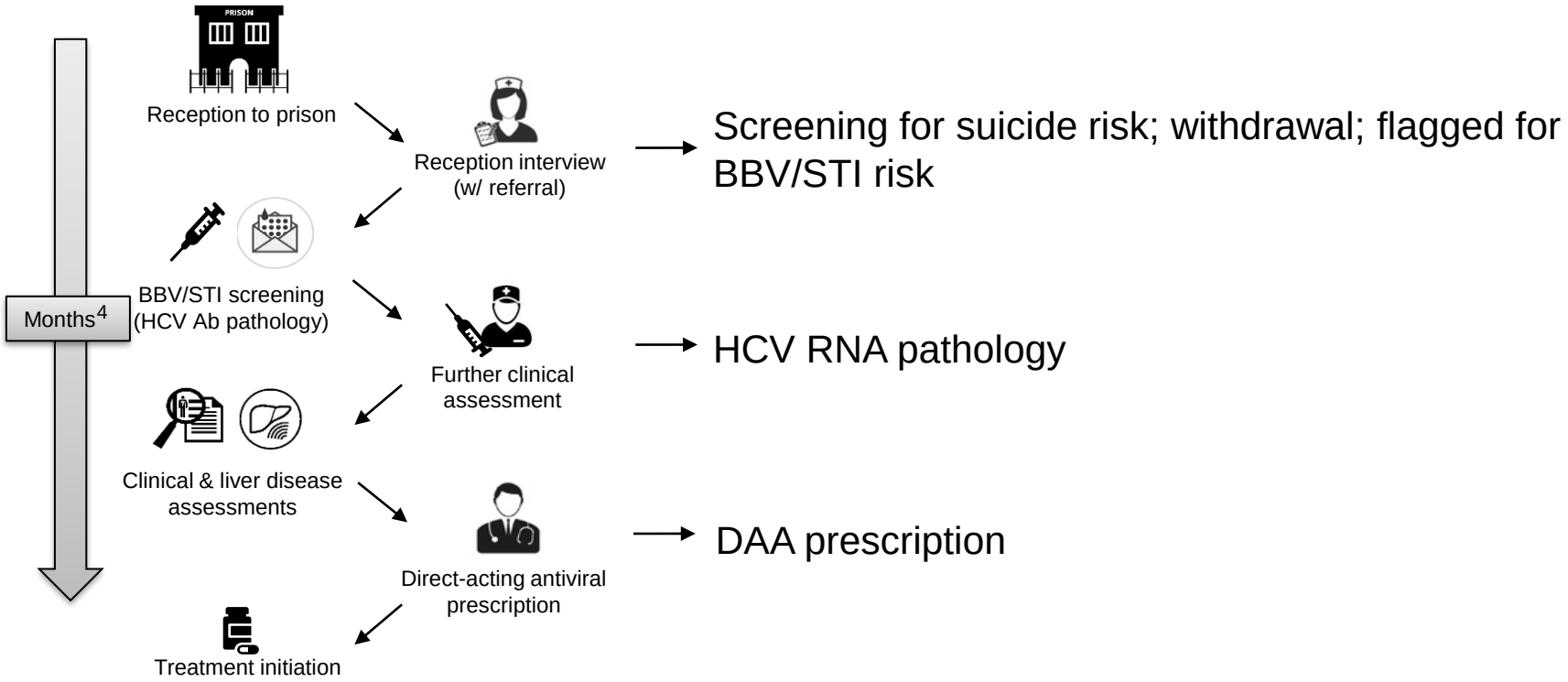
Australian prison setting

- ~110 adult correctional centres
- Unique physical structure, overcrowding
- Highly transient (frequent movements), predominantly short stay
- High rates of drug-related incarceration; high rates of injecting drug use
- High chronic HCV prevalence (10-15%)
- Limited nursing capacity, competing priorities
- Reception centres (prison entrance)
- High throughput approx. 20 per week - 20 per day

Care cascade



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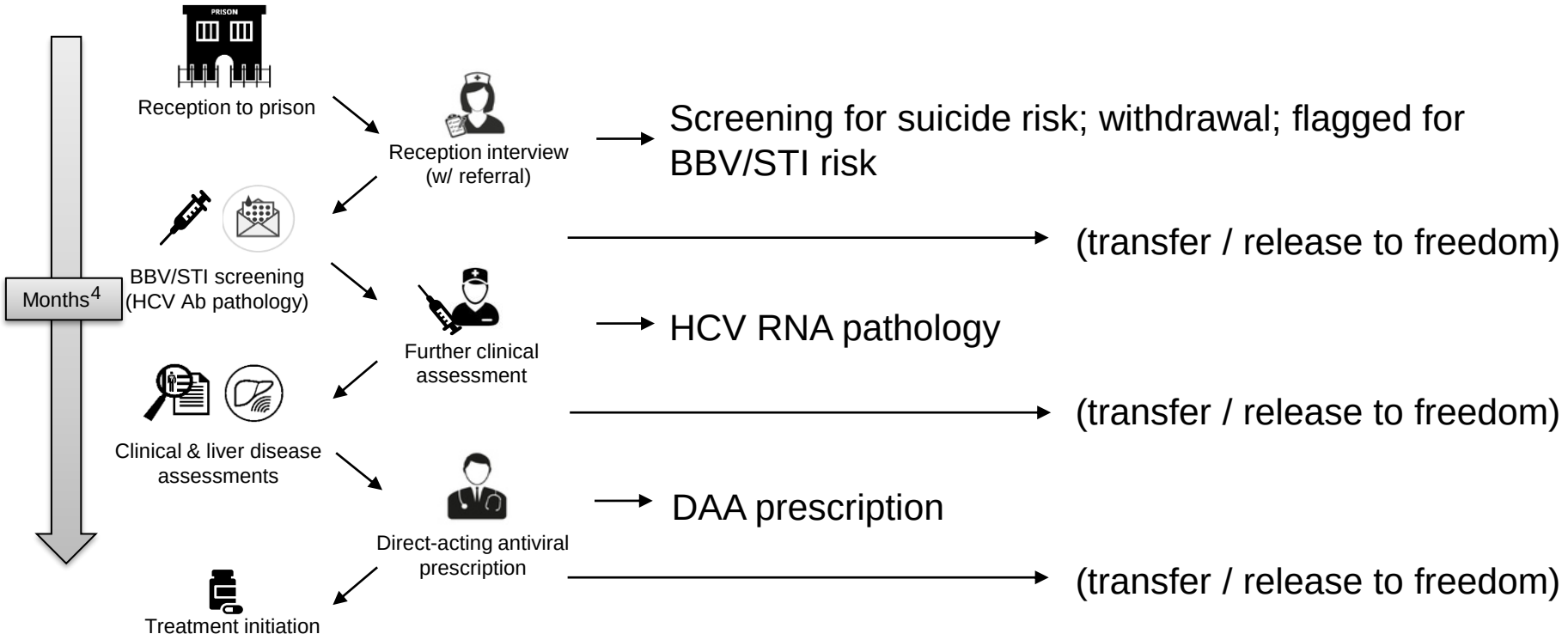
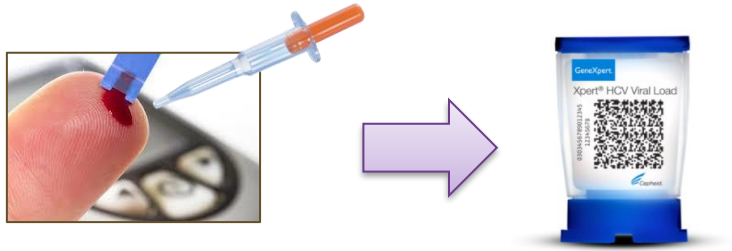


Finger-stick testing for HCV RNA detection



Xpert® HCV VL fingerstick assay

- High sensitivity & specificity (100% & 100% respectively);[5] comparable with traditional laboratory tests
- Quantifiable HCV RNA result in 60 mins
- Potential standalone assay (no prior Ab testing)
- Single-visit diagnosis; one step closer to single-visit test and treat
- Efficiency dependent on prevalence in setting

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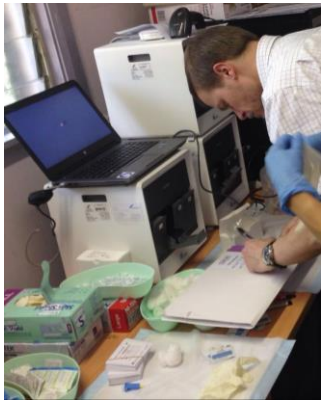
60 mins



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Study objectives

Primary objective: to evaluate a ’one-stop-shop’ intervention integrating point-of-care HCV RNA testing, fibroscan, clinical assessment, and fast-tracked DAA prescription, on treatment uptake among people recently incarcerated

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Primary endpoint: treatment initiation at 12 weeks from enrolment

Secondary objectives:

1. To compare the proportion of people tested for HCV prior to and following the intervention
2. To compare the time taken from enrolment to each step in the care cascade

Participant eligibility

Location: reception prison on the Mid North Coast NSW

Participant eligibility

Inclusion criteria:

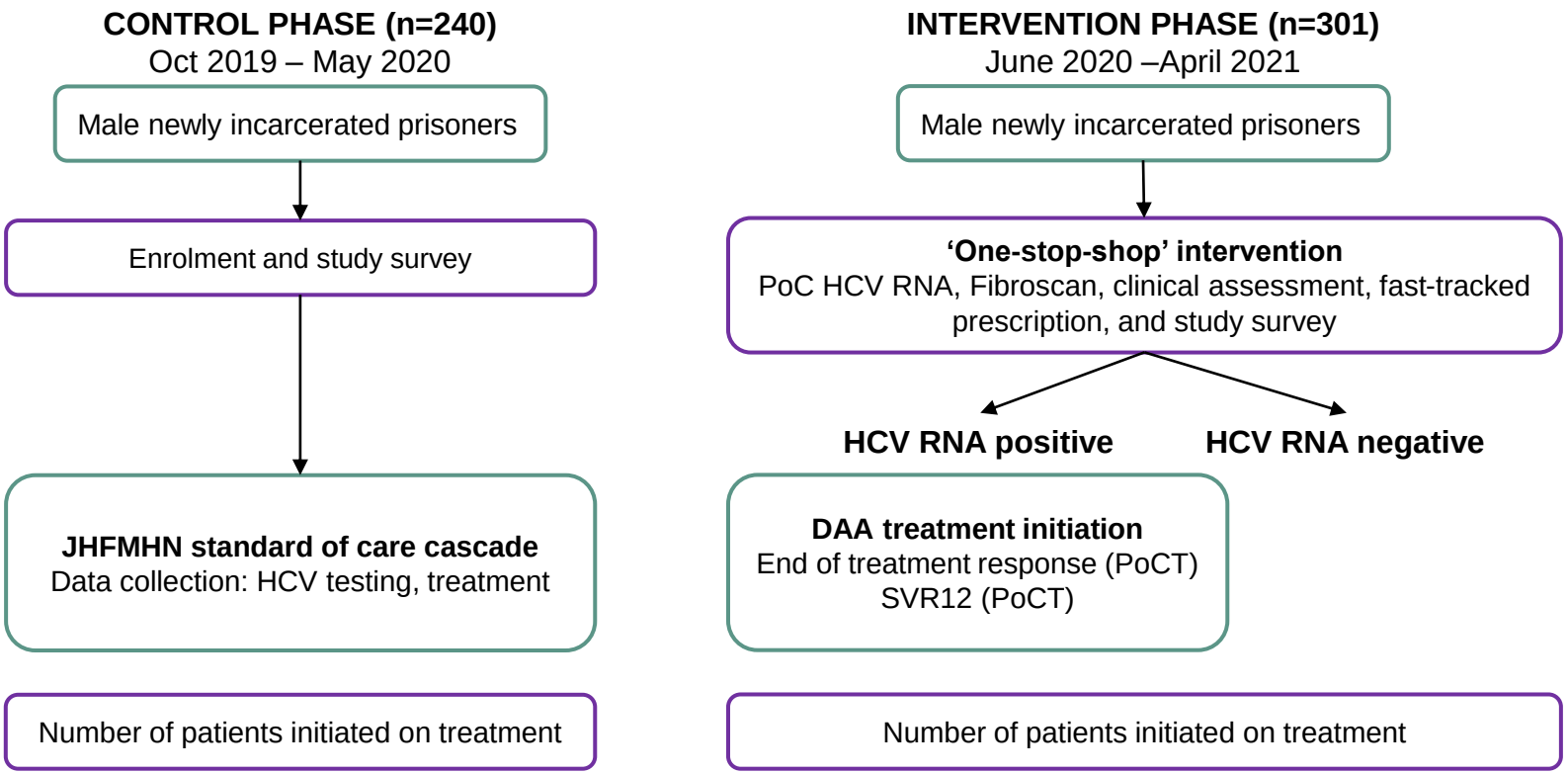
- ≥18 years old
- Newly incarcerated males (within previous 6 weeks);
- DAA treatment naïve.

Exclusion criteria for treatment initiation:

- HBV co-infection;
- Invalid fibroscan;
- Evidence of cirrhosis.

Mid North Coast Correctional Centre

Methods


CONTROL PHASE (n=240)
Oct 2019 – May 2020
Male newly incarcerated prisoners
Enrolment and study survey
JHFMHN standard of care cascade
Data collection: HCV testing, treatment
Number of patients initiated on treatment
INTERVENTION PHASE (n=301)
June 2020 –April 2021
Male newly incarcerated prisoners
'One-stop-shop' intervention
PoC HCV RNA, Fibroscan, clinical assessment, fast-tracked prescription, and study survey
HCV RNA positive
HCV RNA negative
DAA treatment initiation
End of treatment response (PoCT)
SVR12 (PoCT)
Number of patients initiated on treatment

‘One-stop-shop’ intervention

HCV RNA PoC + interview survey + clinical assessment + fibroscan

30-60 mins

Fast-tracked pan-genotypic DAA prescription

~same day

Fast-tracked treatment initiation

~few days

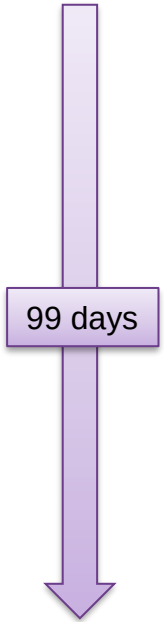
Participant characteristics

	Overall (n=540)		HCV RNA positive (n=48)	
Variable	Control n (%)	Intervention n (%)	Control n (%)	Intervention n (%)
Male, n (%)	239 (100%)	301 (100%)	18 (100%)	30 (100%)
Age, median (IQR)	29 (22-34)	28 (20-34)	24 (20-33)	27 (20-31)
Aboriginal and/or Torres Strait Islander, n (%)	130 (54%)	148 (49%)	13 (72%)	16 (53%)
Previous incarceration, n (%)	191 (80%)	242 (80%)	18 (100%)	29 (97%)
Sentenced, n (%)	41 (17%)	43 (14%)	5 (28%)	5 (17%)
Injecting drug use ever, n (%)	115 (48%)	125 (45%)	18 (100%)	28 (93%)
Injecting drug use in past 6 months, n (%)	84 (35%)	95 (32%)	16 (89%)	23 (77%)
History of OAT				
Never, n (%)	190 (79%)	264 (88%)	10 (56%)	22 (73%)
Yes, but not currently receiving OAT, n (%)	30 (13%)	25 (8%)	6 (33%)	5 (17%)
Currently receiving OAT, n (%)	19 (8%)	12 (4%)	2 (11%)	3 (1%)

Results

Control: standard of care

Event	Number (%)
Enrolled	239
Ever injected (at risk)	115/239 (48%)
HCV Ab / RNA testing	63/239 (26%)
HCV RNA positive	18/63 (29%)
DAA treatment initiated	4/18 (22%)
Treatment completed	Unknown
SVR12 achieved	0/4 (0%)



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99 days

’One-stop-shop’ intervention

Event	Number (%)
Enrolled	301
Ever injected (at risk)	125/301 (42%)
HCV RNA PoC testing	298/301 (99%)
HCV RNA positive	30/298 (10%)
DAA treatment initiated	28/30 (93%)
Treatment completed	15/28 (50%)
SVR12 achieved	11/28 (39%)

6 days

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Discussion

- Extends findings from other prison and community-based studies involving PoC testing
- Funding for a dedicated research nurse and correctional officer; dedicated clinic space
- Combined package of all elements important
- PoC testing is being scaled up in prisons across Australia

Conclusions

- A ‘one-stop-shop’ intervention integrating PoC testing enhanced testing and treatment uptake
- Markedly reduced time & increased efficiencies for treatment initiation
- Overcome key barriers to treatment scale-up in the prison sector
- Continuing to scale-up PoC testing in prisons more broadly will be good for national elimination

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