NZ PrEP

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How it started

- A group of us got together in 2015 and had a discussion about how we could implement our own demonstration project in NZ
- Currently a collaboration between ARSHS,NZAF, Body Positive and the University of Auckland- project is supported by Infectious Diseases Service in Auckland
- Slow start as main stumbling block was getting funding and approval from ADHB –also most of us are not researchers by trade(except Peter Saxton)

Researchers

- Clinical-Sunita Azariah, Suzanne Werder, Rick Franklin, Rose Forster
- Behavioural and qualitative surveys-Peter Saxton
- PrEP Website and research database-Mark Fisher
- Community Engagement –NZAF-Jordon Harris(Kaiarahi),Nick Laing

Process

- Looked at various protocols from overseas-mainly Australian
- Ours is mainly based on Prelude
- Developed draft protocol and participation information sheets, consent forms
- Discussion with ARSHS management as to whether they would support this-cautious endorsement but advised prescribing generic tenofovir/emtricitabine would not be an option within ADHB as no NZ licensed product available

Rationale

- HIV is a serious public health issue
- Numbers of new HIV infections are increasing
- Other STIs such as syphilis are on the rise predominantly in GBM
- Approximately 6.5% of GBM in Auckland are HIV positive-over half of new infections are reported in Auckland
- ARSHS is ideally positioned for this project as sexual health clinics are preferred site of HIV testing for GBM

PrEP

- PrEP or pre-exposure prophylaxis involves taking tenofovir/emtricitabine usually on a daily basis to prevent HIV acquisition
- If taken correctly it prevents 80 to 90% of incident infections compared with controls
- Harms so far appear to be minimal however there is evidence of increased high-risk behaviour and increased incidence of other STIs in some GBM in later analyses of overseas demonstration projects

Aims

- To assess the implementation of a novel intervention-namely PrEP in a sexual health clinic setting to individuals at high risk of HIV acquisition
  - Reduce incident infections
  - Assess feasibility of introducing this intervention
  - Refine clinical protocols to optimise service delivery

Objectives

- Assess acceptability of PrEP -adherence; duration; retention;
- Assess risk behaviours on PrEP including sexual partnering; condom use; STI and HIV incidence
- Analysis of factors (socio-demographic and attitudes) associated with PrEP acceptability, retention and behaviours
- The lived experience of PrEP use including disclosure; stigma; sexual negotiation.

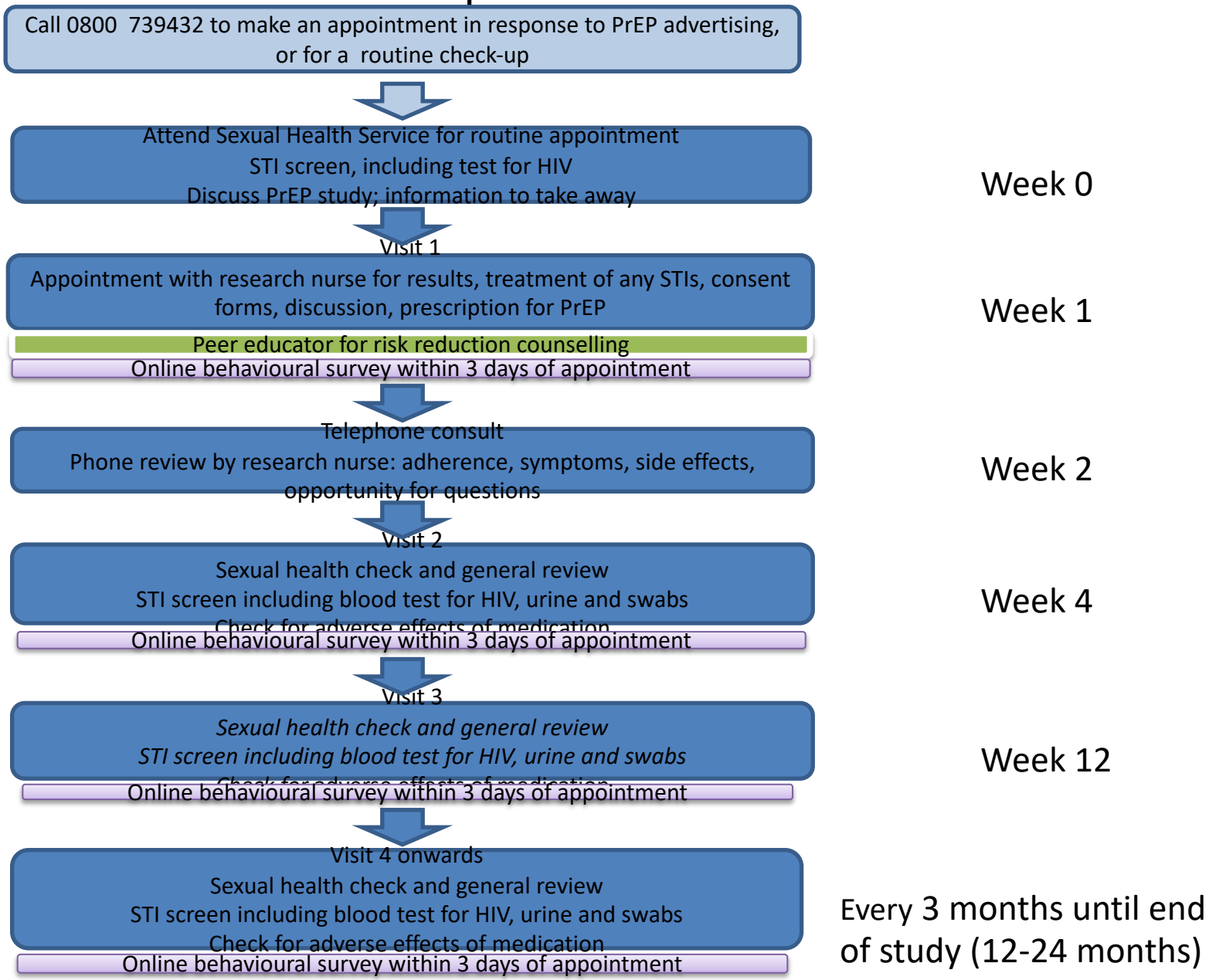
Process (2)

- Draft budget drawn up
- ARSHS management expressed concerns re service capacity-agreed that 150 participants would be feasible within current service volumes and constraints
- Application made to ADHB Trust fund in May 2015-rejected-”Service delivery, not research”
- Gilead kindly agreed to fund medications and research associated costs-Truvada plus 150K(facilitated by Rick Franklin)
- ADHB is funding costs associated with usual patient care including clinic visits, STI and HIV testing, clinician time
- NZAF has generously agreed to up to 30k of additional funding as required-so far not tagged to any specific component
- Independent source of funding to be sought for behavioural component-HRC application (Peter Saxton)

Protocol

- Open-label single-arm treatment evaluation study-150 participants
- GBM at elevated risk of HIV will be recruited via: routine clinic visits to ARSHS, websites, targeted promotion, community partnerships
- Study will be powered to detect ethnic differences in adherence and retention-if 20% of participants are Maori, we have 72% power to detect suboptimal study retention compared to non-Maori
- Duration 24 months

Participant visit schedule



Where we are at currently

- Ethics approval from Northern health and Disability ethics committee obtained
- ARSHS management sign-off completed
- Waiting ADHB research office approval sign-off-budget has been approved(Suzanne W facilitating)
- Waiting to see if HRC application has been approved for on-line behavioural survey and qualitative research(Peter S)
- Clinical protocols etc. are being drafted (Rose F)
- Development of Research database in process(Mark F)
- Staff training sessions booked in for later this year