

15th Annual Conference of the
National HIV Nurses Association (NHIVNA)



National HIV Nurses Association

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27-28 June 2013- The International Convention Centre, Birmingham

TOP 10

Highlights in
2012-13

and their impact on
Nursing

Lorraine Lewis and Maxine Owen
27th June 2013

Treatment as prevention (TasP)

Commencing Antiretroviral therapy in HIV positive individuals regardless of CD4 count in order to suppress levels of virus making them less likely to transmit HIV to HIV negative sexual partners

Background

- The number of new infections in UK is rising with more than 3,800 in 2010₁
- Care cost in UK approx. £762m₂
- “the initiation of treatment on diagnosis, regardless of CD4 count might well be necessary to achieve control of HIV transmission”₃
- “that clinicians discuss the benefits of early treatment uptake as a prophylaxis to protect sexual partners”₃

1.MRC CTU Briefing paper, Nov 2012.Issue 51

2.Perry N (2013) Preventing the spread of HIV infection (online) Nursing Times

3.Cairns G (2013) HIV incidence in gay men unchanged in England and Wales, despite more testing

Treatment as prevention (TasP)

- Treatment and Prevention have converged
- Efficacy evidence justifies its use
- Further research is needed
- Requires higher levels of testing, linkage and retention in care and access to quality care
- Lots of challenges₁

1. http://www.iapac.org/tasp_prep/assets/TPS12_consensus.pdf

Pre-Exposure Prophylaxis (PrEP)

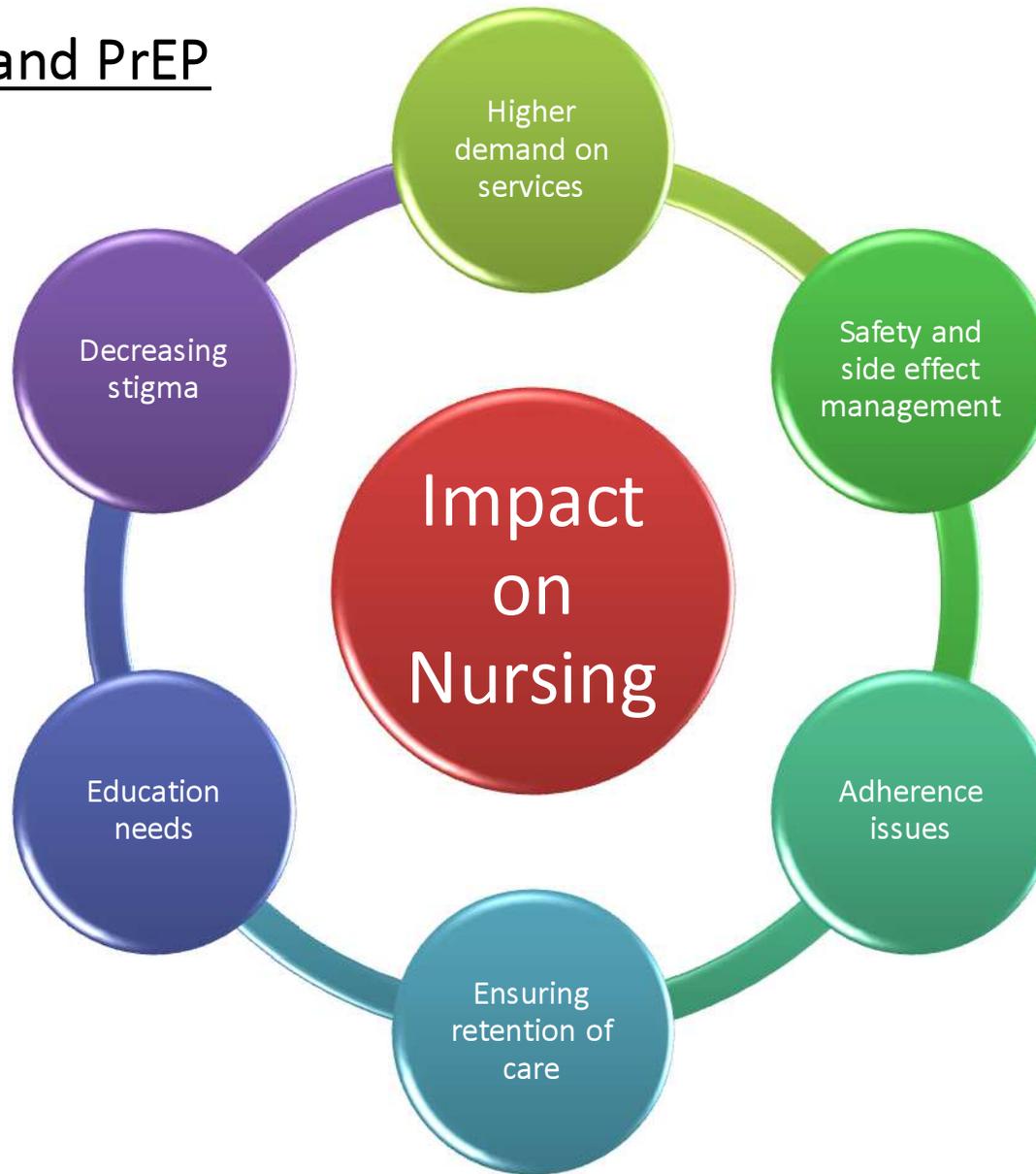
HIV negative individuals taking antiretrovirals to reduce the risk of becoming infected if they are exposed to the virus¹

1.MRCTU Briefing paper, Nov 2012.Issue 51

Pre-Exposure Prophylaxis (PrEP)

- The evidence of daily oral PrEP efficacy and safety supports its use in high risk groups
- Safety monitoring is required
- Should be part of risk reduction package
- Requires support for adherence
- Lots of challenges

TasP and PrEP



New BHIVA pregnancy guidelines

- Efavirenz - can be both continued and commenced during pregnancy
- Women not needing ART for themselves should commence it by week 14 of pregnancy if VL >30k.
- NVD if on ART and VL<50 at week 36
- PLCS on AZT monotherapy regardless of VL or if VL >400 regardless of ART₁

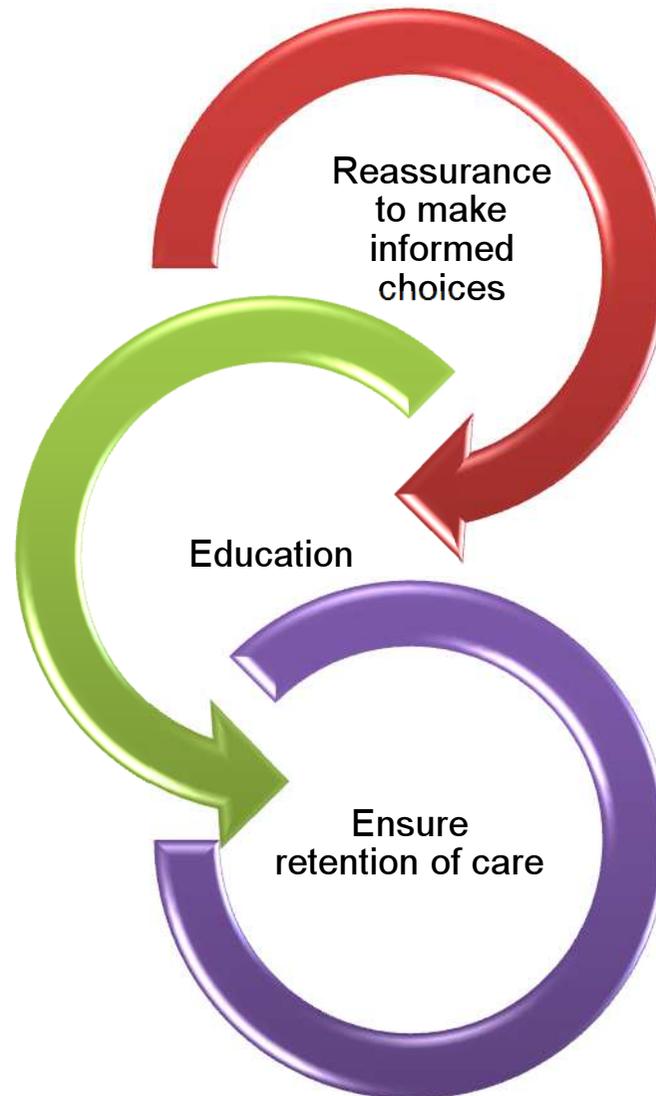
1.<http://www.bhiva.org/PregnantWomen2012.aspx>

Infant Feeding

- All mothers are advised to exclusively formula feed
- Mothers who choose to breastfeed should be supported to do so and not referred to child protection teams
- Maternal ART continued until 1 wk. after breastfeeding stopped
- Prolonged infant prophylaxis not recommended
- Monthly maternal VL and HIV PCR, cDNA or VL₁

1.<http://www.bhiva.org/PregnantWomen2012.aspx>

Pregnancy Guidelines
Impact on Nursing



Functional HIV Cure after very early ART of an infected child

- CROI 2013
- Infant born by NVD AT 35wks, Maternal HIV test during labour positive
- No ARV drugs given during labour & delivery as rapid
- Baby started on AZT/3TC/NVP
- Infant HIV infection confirmed
- Undetectable VL achieved and maintained

Functional HIV Cure after very early ART of an infected child

- Infant lost to F/up at 18mths and returned to care at 23 months
- No ART for 5mths , infant VL was undetectable
- Infant was HIV negative by Elisa and HIV DNA PCR was negative
- Multiple assays were performed
- At 2 and 2.2 yrs and off ART for 8 and 10 mths western blot was HIV antibody negative

Functional Cure
Implications for Nursing

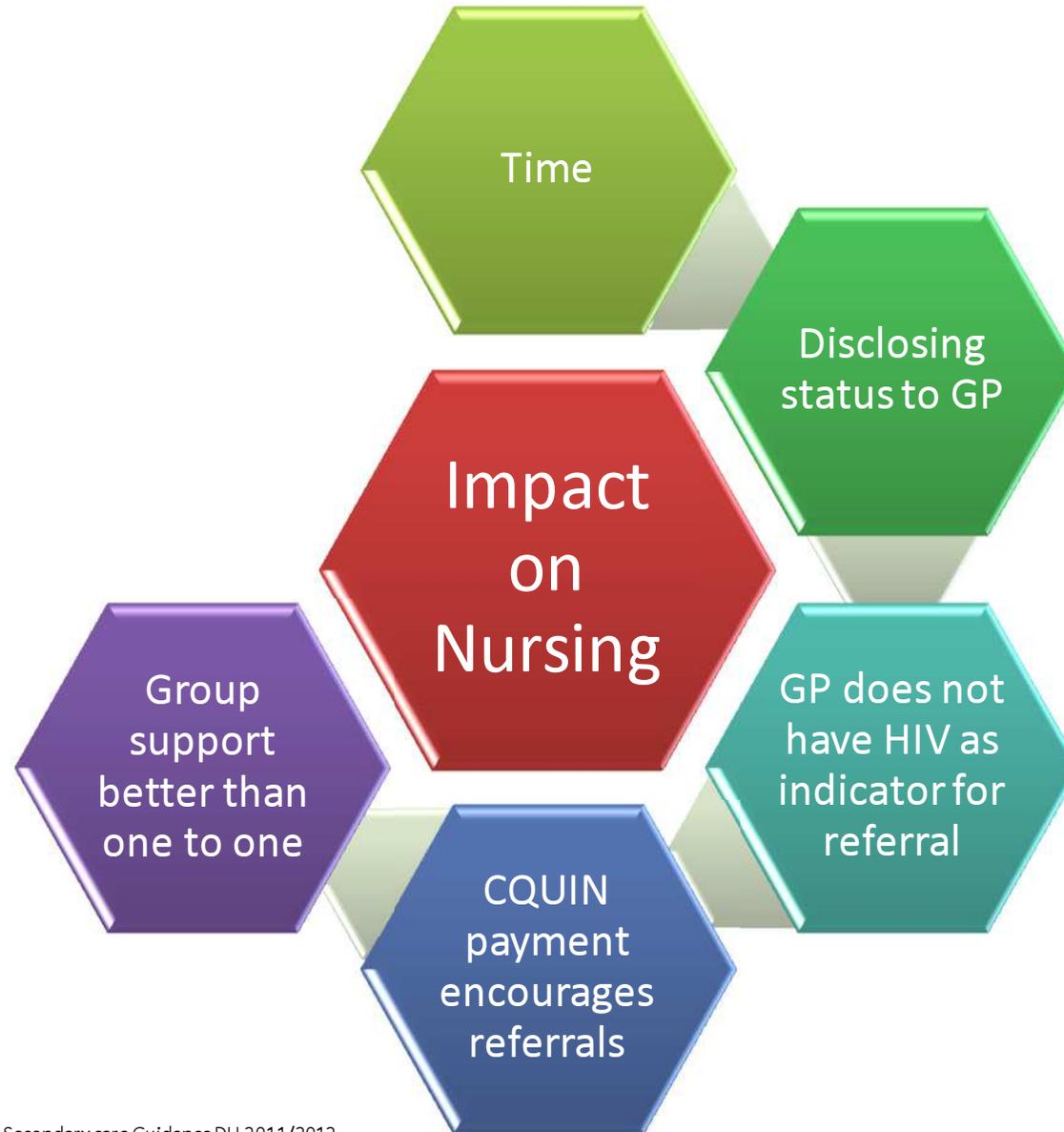


Deaths related to smoking in HIV 1 Infected Individuals

- Danish study 47% of HIV positive cohort smoked compared to 21% who were not HIV positive.
- Life expectancy, 35yr old HIV +ve person was 62.6 yrs for smokers, 69.1 yrs for previous smokers and 78.4 yrs for never-smokers.
- HIV +ve smokers had higher all-cause mortality and higher non-AIDS related mortality. AIDS related deaths were more likely among smokers than the other groups.
- More than 60% of deaths in the HIV cohort were due to factors related to smoking.¹

1.Mortality attributable to Smoking Among HIV-1-Infected Individuals:A Nationwide, population-Based Cohort Study. Helleberg M et al. Clinical Infectious Diseases 2013 Mar;56(5):727-34.

Smoking



The stop smoking Interventions in Secondary care Guidance DH 2011/2012.

Audience Participation !



GENERICS

Copies of innovator drugs



I searched
for tablets !

RELEVANCE and SAFETY ?

- Some HIV drugs off / coming off patent
- The public purse is being stretched and HIV drugs are very expensive.
- Cheaper, non-branded drugs (on average 80% - 85% lower than the brand name) ¹

- Generics already make a big contribution to managing HIV in the developing world
- MSF and PEPFAR say they are quality assured by the US FDA and WHO and are as effective as brand name drugs ²
- FDA say those approved by them have met the same rigid standards as the innovator drug and are bioequivalent ²

ARVs patent expiry

| Approved Name | Manufacturer | Year | UK | UK-SPC |
|--|-------------------------|-------------|------------|------------------------|
| Abacavir | GSK | 2014 | 21/12/2010 | 27/06/2014 |
| Abacavir + Lamivudine | GSK | 2019 | 27/03/2016 | 16/12/2019 |
| Atazanavir sulphate | BMS | 2019 | 13/04/2017 | 01/03/2019 |
| Efavirenz | BMS | 2013 | 02/08/2013 | 19/11/2013 |
| Darunavir | Janssen-Cilag | 2018 | 23/08/2013 | 23/08/2018 |
| Emtricitabine | Gilead | 2016 | 30/01/2011 | 30/01/2016 |
| Etravirine | Janssen-Cilag | 2023 | 31/10/2019 | 28/08/2023 |
| Lamivudine | Glaxo Wellcome | 2011 | 08/02/2010 | 27/02/2011 |
| Lopinavir | Abbott | 2015 | 15/12/2013 | 12/12/2015 |
| Maraviroc | Pfizer | 2022 | 08/05/2021 | 18/09/2022 |
| Nevirapine | Boehringer Ingelheim | 2012 | 16/11/2010 | 22/06/2013 (paed extn) |
| Ritonavir | Abbott | 2015 | 16/12/2013 | 12/12/2015 |
| Rotonavir + Lopinavir | Abbott | 2016 | 16/10/2013 | 19/03/2016 |
| Tenofovir + Efavirenz + Emtricitabine | Gilead | 2018 | 02/08/2013 | 02/08/2018 |
| Tenofovir disoproxil fumarate | Gilead | 2022 | 24/07/2017 | 24/07/2022 |
| Zidovudine | Wellcome | 2006 | 14/03/2006 | |
| Zidovudine + Lamivudine | GSK | 2013 | 11/05/2012 | 17/03/2013 |

IMPACT FOR NURSES

- Be aware of generics available in your area and how they will be used
- Inform patients – they need to know and understand any changes to regimen
- Encourage patients to learn names of medication rather than just colour and shape

- Ensure 'yellow cards' are completed where there is a signal to do so
- Have a balanced view about generics – we need to safely cut costs, particularly if we are to afford newer, more expensive treatments in the future
- Work together with Drs, Pharmacists, Finance, Managers and above all, patients
- Be an advocate for those patients who are concerned about switching to generics



OK, which one of you said it ?!

THE FRANCIS REPORT ³

- Robert Francis QC published his inquiry report into Mid-Staffordshire NHS Foundation Trust in February 2010
- The inquiry was as a result of concerns raised about mortality rates / poor standards of care
- The *Cure the NHS* Group had ensured the concerns remained in the public eye

EXAMPLES OF POOR CARE

- Requests for toilet not responded to
- Patients left on toilets or commodes too long
- Patients left to care for themselves – often in the final days of their life
- Staff attitudes dismissive / didn't seem to care



BIRMINGHAM HEARTLANDS **HIV SERVICE** **NHS**



“ However difficult the circumstances, there is no excuse for staff to treat patients in the manner described by some witnesses to the Inquiry. Respect for dignity must be a priority of care and must be at the forefront of clinicians minds”

Francis 2010

“ The impact of this on them [patients] and their families is almost unimaginable. Taken, individually, many of the accounts I received indicated a standard of care which was totally unacceptable. Together, they demonstrate a systematic failure of the provision of good care “

Francis 2010

Surely impact for nurses is clear !

“ If there is one lesson to be learnt, I suggest that people must always come before numbers. It is the individual experiences that lie behind statistics and benchmarks and action plans that really matter, and that is what must never be forgotten when policies are being made and implemented”

Francis 2010

Pills, Pennies and Politics !

Research continues to produce new ARVs and tablet combinations such as –

- STRIBILD – quad pill containing elvitegravir / cobicistat / emtricitabine / tenofovir
- DOLUTEGRAVIR – an integrase inhibitor awaiting FDA approval
- ELVITEGRAVIR and COBICISTAT – at present FDA rejected application for approval for stand-alone use

Pennies !

“... in the current economic climate, containing and reducing annual costs without affecting the current high standards of care and treatment outcomes will be an immense challenge to commissioners, healthcare professionals and patients alike. A collaborative approach is required” ⁴

Still counting !

“... the cost of ARVs remains the major factor contributing to treatment and care costs. With the future availability of generic drugs and the introduction of a standard tariff for HIV services (in England), clinicians and patients will be faced with difficult choices about the value and benefit of different ARV drugs” ⁴

And politics ?!!!!

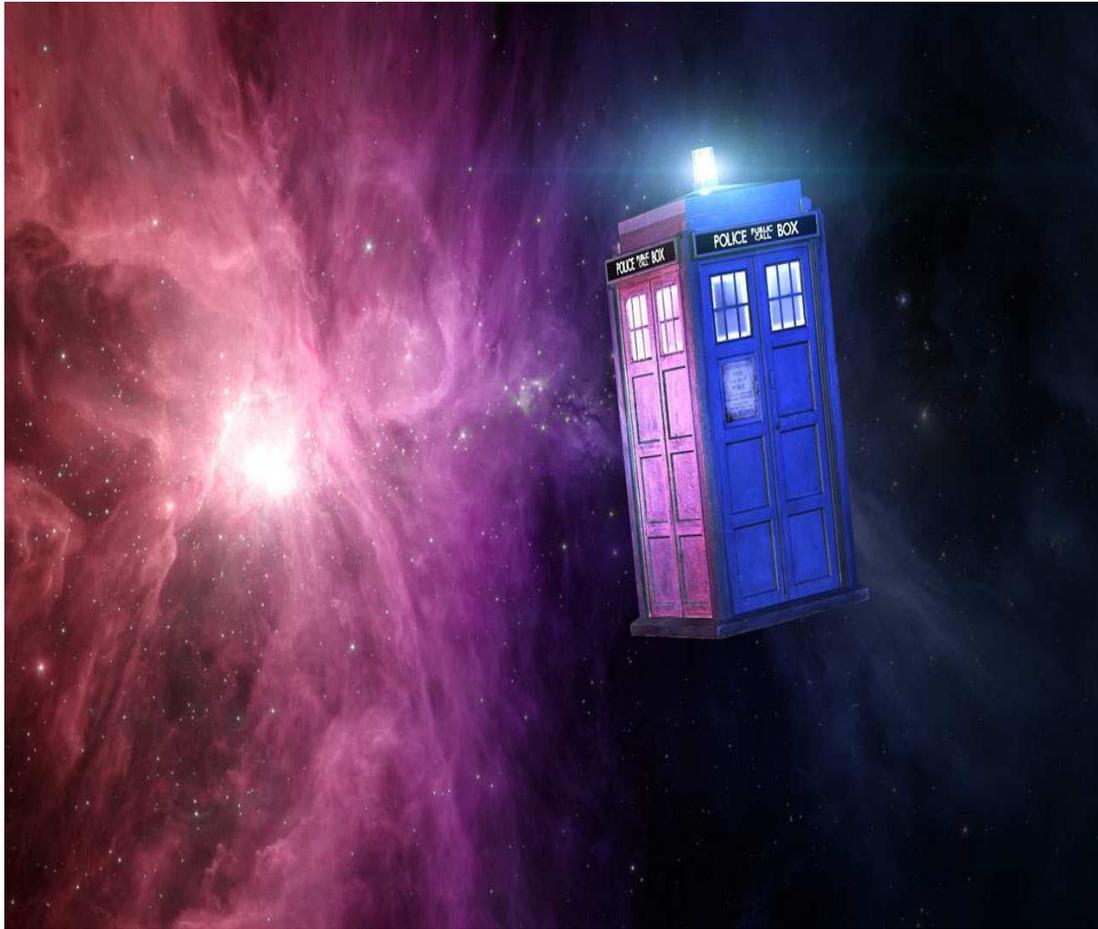
“... commissioning arrangements and local drug costs will and should influence ART choice where outcomes, across a range of clinical measures, are equivalent between individual drugs in the treatment of defined patient populations. The Writing Group, however, believes that reducing treatment costs should not be at the cost of an increased risk of poorer treatment outcomes and quality of care”⁴

IMPACT FOR NURSES

- Make yourself aware of local policies around prescribing – keep abreast of changes
- What is available in your hospital / Trust formulary?
- Patients may no longer be able to have their choice of ARVs
- Help to educate patients about these changes



HEPATITIS C

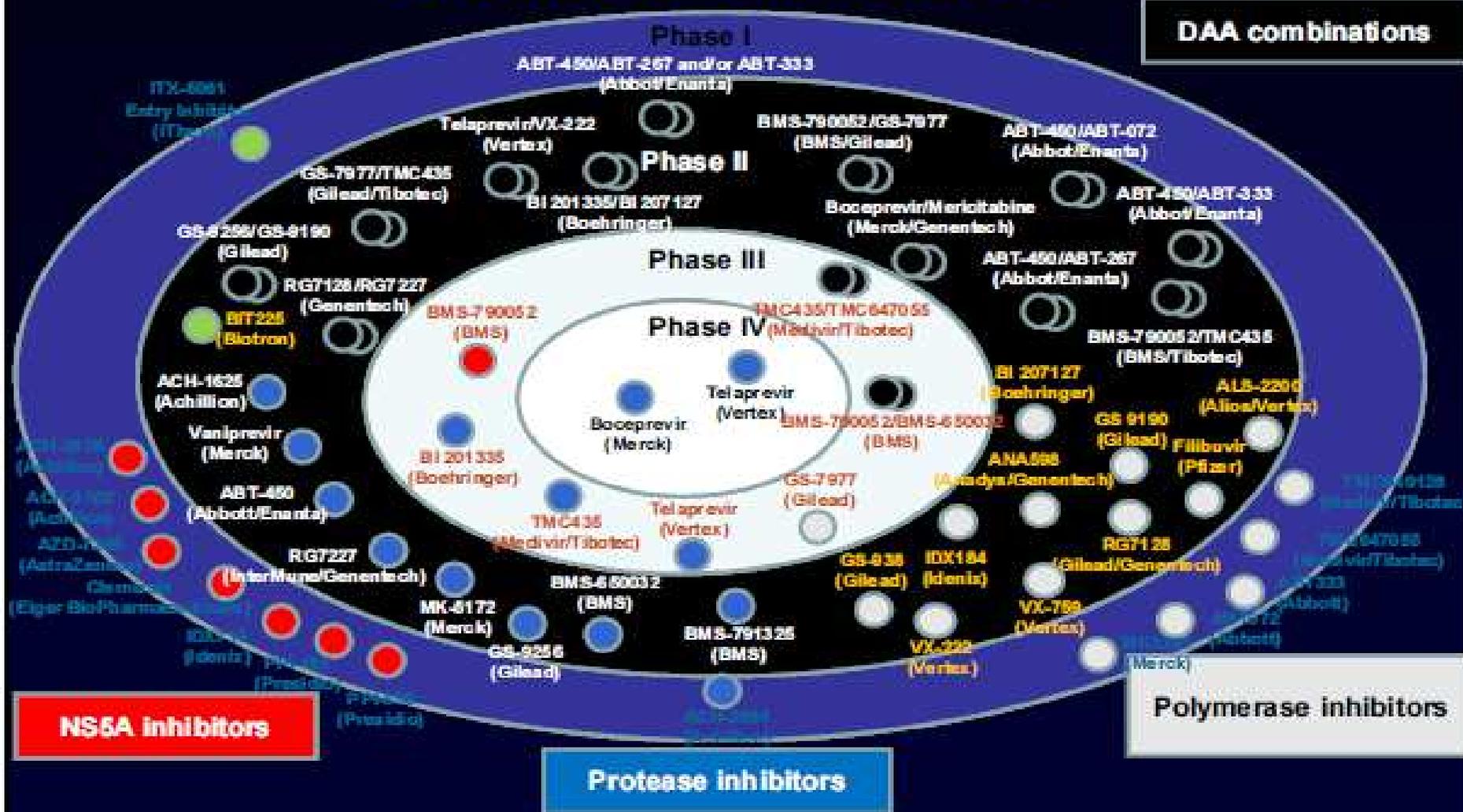


DR WHO ?



Hepatitis C pipeline

DAA combinations



Franciscus, A. Hepatitis C Treatments in Current Clinical Development, 17 October 2012, available at: http://www.hcvadvocate.org/hepatitis/hepC/HCVDrugs_2012.pdf

HEP C: To Treat or Not to Treat ?

And this isn't all there is to think about !

| | | |
|--|----------------------------|--------------------------------------|
| Genotype | Drug interactions | Duration of infection |
| Personal plans (marriage, pregnancy) | Age | Family and other support |
| Patient mindset | Adherence | Occupation |
| Side effects | Likelihood of re-infection | Contraindications & comorbidities |

IMPACT FOR NURSES



Help patients understand the balance

Over to you !

Or else it's my highlight for
2012 / 2013 !!!









*Thank
You*

- ❖ Justine Barnes and Kate Gandhi
- ❖ Lorraine Lewis
- ❖ Sandra Harris
- ❖ Elizabeth Stephens – for your kindness
- ❖ Jo Logan
- ❖ Migs, Jake and Alice
- ❖ Isabella Rose Owen – for bringing me such joy

References

- 1 <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>
- 2 <http://www.bbc.co.uk/news/health-21012160>
- 3 http://www.midstaffsinquiry.com/assets/docs/Inquiry_Report-Vol1.pdf
- 4 British HIV Association guidelines for the treatment of HIV-1- positive adults with antiretroviral therapy 2012 p9 1.4 Resource use
- 5 <http://www.nhivna.org/documents/Conferences/2013/StudyDays/130308/Nelson.pdf>

Other references that have informed the talk

- <http://nursingstandard.rcnpublishing.co.uk/news-and-opinion/news/apathy-stops-many-of-us-from-exposing-poor-care/>
- <http://www.hivandhepatitis.com/hiv-aids/hiv-aids-topics/hiv-treatment/4016-croi-2013-new-pro-drug-tenofovir-alafenamide-appears-equally-effective-but-better-tolerated>
- <http://www.londonspecialisedcommissioning.nhs.uk/documents/371.pdf>

All references accessed between March 2013 and June 25th 2013