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Blood Borne Viruses & Healthcare Workers: Would a new policy mean the end of lookbacks?

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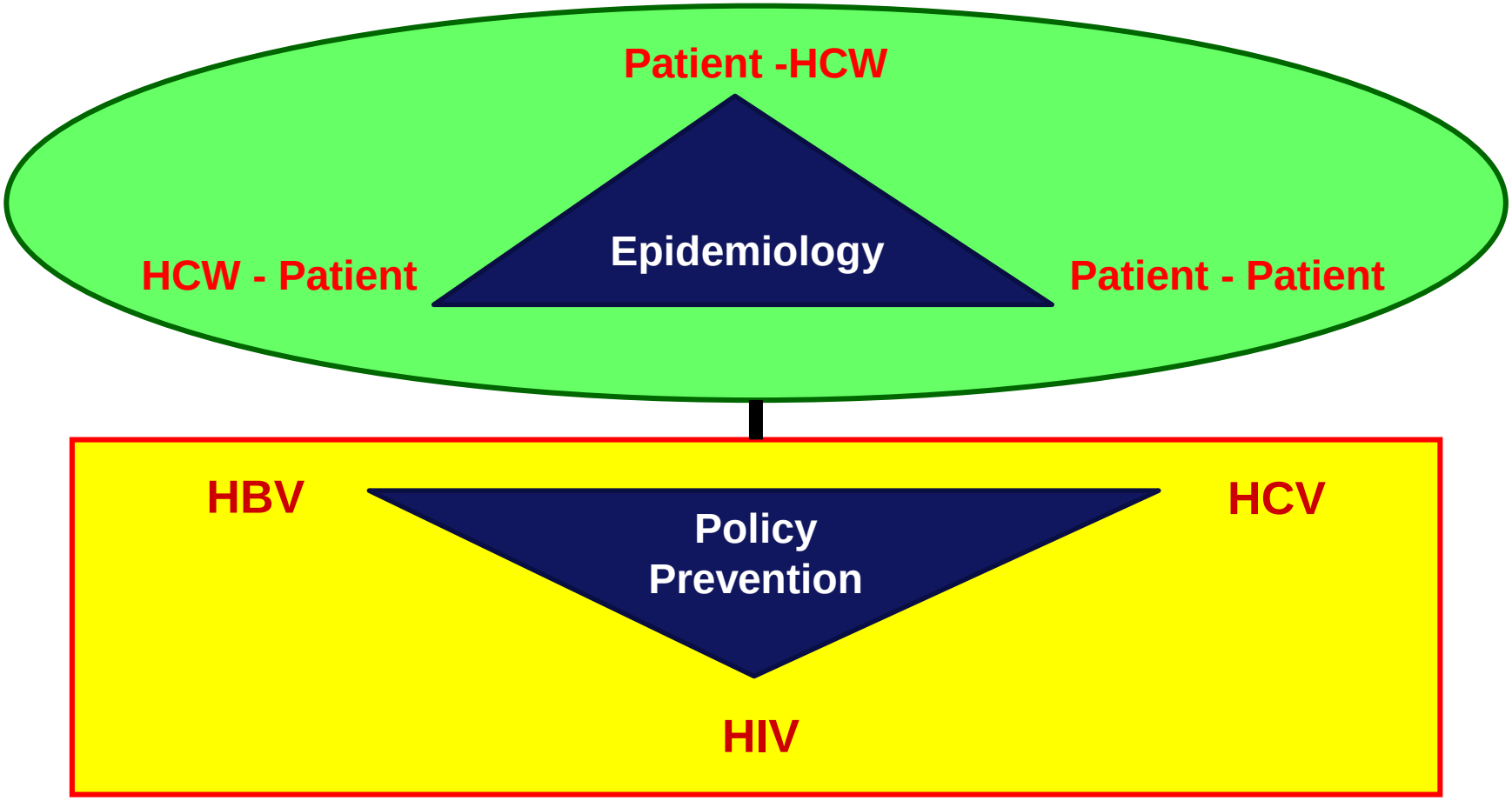
Bloodborne viruses in the healthcare setting



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Healthcare worker-to-patient bloodborne virus transmissions

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Exposure prone procedure – Definition (1)

- ‘Those invasive procedures where there is a risk that injury to the worker may result in the exposure of the patient’s open tissues to the blood of the worker (bleed-back).

- These include procedures where the worker’s gloved hands may be in contact with sharp instruments, needle tips or sharp tissues (e.g. spicules of bone or teeth) inside a patient’s open body cavity, wound or confined anatomical space where the **hands or fingertips may not be completely visible at all times**.’

Source: UK Health Departments. HIV Infected Health Care Workers: Guidance on Management and Patient Notification. July 2005

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Exposure prone procedure: categories

3

- Procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages, and in which there is a distinct risk of injury to the worker's gloved hands from sharp instruments and/or tissues.
- eg Hysterectomy; caesarean section; open cardiac surgical procedures

2

- Procedures where the fingertips may not be visible at all times but injury to the worker's gloved hands from sharp instruments and/or tissues is unlikely.
- eg Routine tooth extraction; appendicectomy

1

- Procedures where the hands and fingertips of the worker are usually visible and outside the body most of the time and the possibility of injury to the worker's gloved hands from sharp instruments and/or tissues is slight.
- eg Local anaesthetic injection in dentistry; removal of haemorrhoids

Non-EPPs

- Negligible risk provided routine infection control procedures adhered to at all times
- eg Venepuncture; minor surface suturing; simple endoscopic procedures

Source: UK Health Departments. HIV Infected Health Care Workers: Guidance on Management and Patient Notification. July 2005

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Patient Notification Exercises

Patient notification exercises meet three very distinct purposes:

- To ensure that, as far as is practicable, all patients operated on by an infected HCW are notified of the risk they may have been exposed to.
- To detect any patients who may have been infected in order to offer them the necessary care and to prevent onward viral transmission.
- To collect epidemiological data useful in refining current understanding on risk estimates.

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HCW guidance

Health clearance

HIV guidance

HBV guidance

HCV guidance

UK National policies

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Health Clearance for TB, HBV, HCV and HIV (1)

- Applies to new healthcare workers, which includes:
  - HCWs new to the NHS
  - HCWs moving to a post or training that involves EPPs
  - Returning HCWs, depending on activities engaged in while away from the health service
- Locum/temporary staff:
  - Occupational health checks,
  - Same standard, should be
  - Part of pre-employment checks conducted by providers of temporary staff, regardless of previous NHS employment.
- Independent healthcare sector:
  - NHS Trusts arranging for NHS patients treatment by non-NHS hospitals including independent-sector treatment centres, follow same guidance.
  - Students in training covered by the same policy

Source: Department of Health. Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers. March 2007

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Health Clearance for HBV, HCV and HIV (2)

1) Standard health clearance:

- Completed on appointment
- Checks for tuberculosis disease/immunity
- Offered hepatitis B immunisation, with post-immunisation testing of response
- Offer of tests for hepatitis C and HIV

2) Additional health clearance - for new healthcare workers who will perform EPPs

- Means being non-infectious for:
  - HIV (antibody negative)
  - Hepatitis B (surface antigen negative or, if positive, e-antigen negative with a viral load of 10^3 genome equivalents/ml or less)
  - Hepatitis C (antibody negative or, if positive, negative for hepatitis C RNA)
- Checks should be completed before confirmation of an appointment to an EPP post, as the healthcare worker will be ineligible if found to be infectious

Source: Department of Health. Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers. March 2007

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Specific policies

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UK policy on BBV infected HCWs

	HIV	Hepatitis B	Hepatitis C
Restriction of practice	Yes	Yes, No if HBV e-antigen -ve with viral load below 10^3 geq/ml.	Yes
Return to exposure prone procedures?	Yes Set criteria	Yes, if HBV e-antigen -ve, AND following natural suppression of HBV DNA to $<10^3$ geq/ml OR with suppression sustained $<10^3$ geq/ml for a period of 12 months after cessation of therapy OR with suppression to $<10^3$ geq/ml whilst on antiviral therapy provided pre-treatment viral load between 10^3 and 10^5 geq/ml.	Yes, if, following treatment, they remain HCV RNA negative for at least 6 months after cessation of treatment and should still be HCV RNA negative a further 6 months later.
Patient notification after HCW to patient transmission or 'other relevant considerations'?	Yes	Yes	Yes
Patient notification if no HCW to patient transmission?	Yes, category 3 EPPs only.	No	No

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UK policy: HIV infected healthcare workers

- Policy produced by Expert Advisory Group on AIDS.
- HCW-to-patient transmissions limited to EPPs.
- HIV-infected HCWs must not rely on their own assessment of the risk they pose to patients, but should seek advice.
- HIV-infected HCWs are restricted from performing EPPs.
- If HCW believes infected with HIV must seek confidential HIV test e.g.
  - Unprotected sex between men;
  - Unprotected sex in, or with a person who had been exposed in, a country where transmission of HIV through sex between men and women is common;
  - Shared injecting equipment whilst misusing drugs;
  - Invasive medical, surgical, dental or midwifery procedures, either as practitioner or patient, in parts of the world where infection control precautions may have been inadequate, or with populations with a high prevalence of HIV infection;
  - Significant occupational exposure to HIV infected material in any circumstances;
  - Additionally, a person who has had unprotected sex with someone in any of the above categories may also have been exposed to HIV infection.
- UKAP advises on need for a patient notification exercise

Source: Department of Health, HIV-infected health care workers: Guidance on management and patient notification. July 2005

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Evidence for change in policy

- Policy to restrict practice of HIV-infected HCWs introduced at a time when much less was known about risk of transmission
- No documented cases of HIV transmission from HCW →patient (in the UK); four reported incidents worldwide.
- Data from UK PNE suggest the risk is low (retrospective US data also suggests risk is low)
- Current policy does not take into account viral suppression achievable on cART
- UK policy is more conservative than some countries (but in line with others)

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The Management of HIV infected HCWs who perform EPPs (January 2014)

HIV infected HCWs are permitted to perform EPPs if

- on effective cART and have a plasma viral load <200 copies/ml, **or**
- an elite controller, **and**
- subject to viral load monitoring every 3 months, **and**
- under the joint supervision of a treating and occupational physician**, and**
- registered with the UKAP Occupational Health Register (UKAP-OHR)

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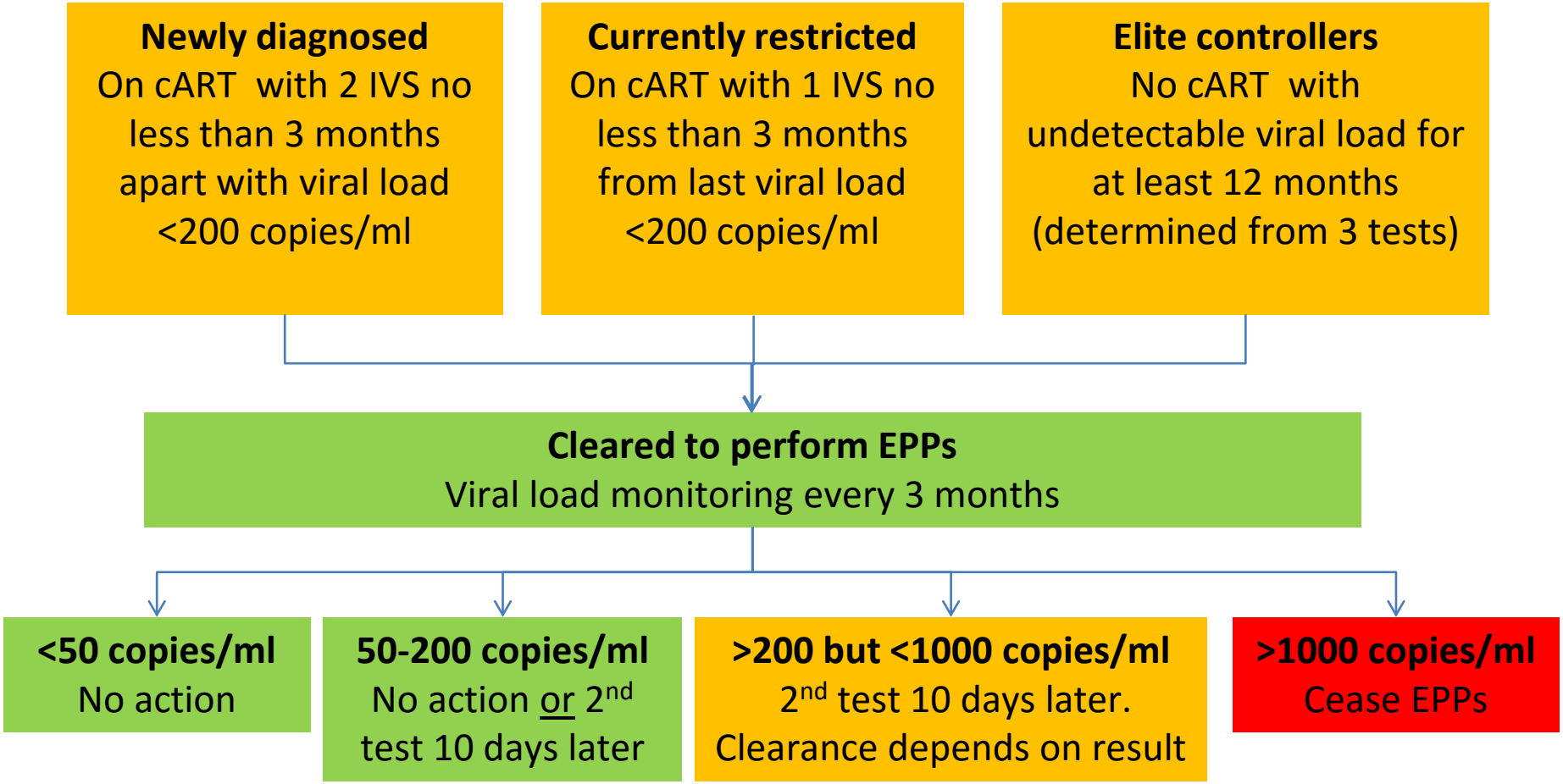
Eligibility and Monitoring



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Benefits to the infected HCW

- Professional security – no restriction from clinical duties subject to meeting the eligibility criteria
- Realistic and achievable eligibility criteria
- No subdivision of EPPs for clarity and practicality
- Flexibility for viral load testing outwith OH services

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Benefits to the infected HCW (cont)

- Medical support to manage their infection (including benefits from cART)
- Guidance on preventing transmission of the virus to others through personal behaviour or accidental exposure
- Confidentiality is maintained

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Responsibilities of the infected HCW

- Registration of details and monitoring data on UKAP-OHR
- The release of monitoring information to occupational and treating physicians
- Attending OH and providing IVS for viral load monitoring at appointed times
- Seeking advice if change of health may affect fitness to practice
- Notifying the treating physician if there has been interruption to therapy of sub-optimal adherence
- Notifying OH when changing practice or place of employment

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Benefits to the wider NHS

Earlier testing amongst HCWs that carry out EPPs has additional public health and cost benefits

- Avoids onward transmission
- Reduces the number (and extent) of PNE
- Retains qualified and skilled HCWs in the career they have trained for
- Avoids legal challenges
- Reduces the fear amongst HCWs of HIV and the potential for transmission from HCW to their patient

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Responsibility for monitoring conti~

The designated consultant occupational physician responsible for;

- ensuring testing in accordance with protocol and timings are followed;
- reacting promptly to any alerts received via UKAP-OHR;
- taking appropriate action if breach of monitoring e.g. notifying the relevant manager of the HCW's non-attendance and restriction from EPP practice;
- ensuring IVS samples collected, tested and results obtained in timely manner

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Responsibility for monitoring conti~

- interpreting the viral load results in relation to clearance to perform EPPs
- notifying the HCW they are fit to perform EPP, and manager of their fitness to practice.
- ensuring that the UKAP-OHR is updated in a timely manner;
- advising the HCW and the employer, on an ongoing basis, whether the HCW is fit to perform EPPs;
- timely liaison with treating physicians, when required.

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Discussion question

How would you manage a healthcare worker who has sustained a needle-stick injury from a patient who is HIV+ve but has been on long-term continuous anti-retroviral therapy and has long-term undetectable viral load?

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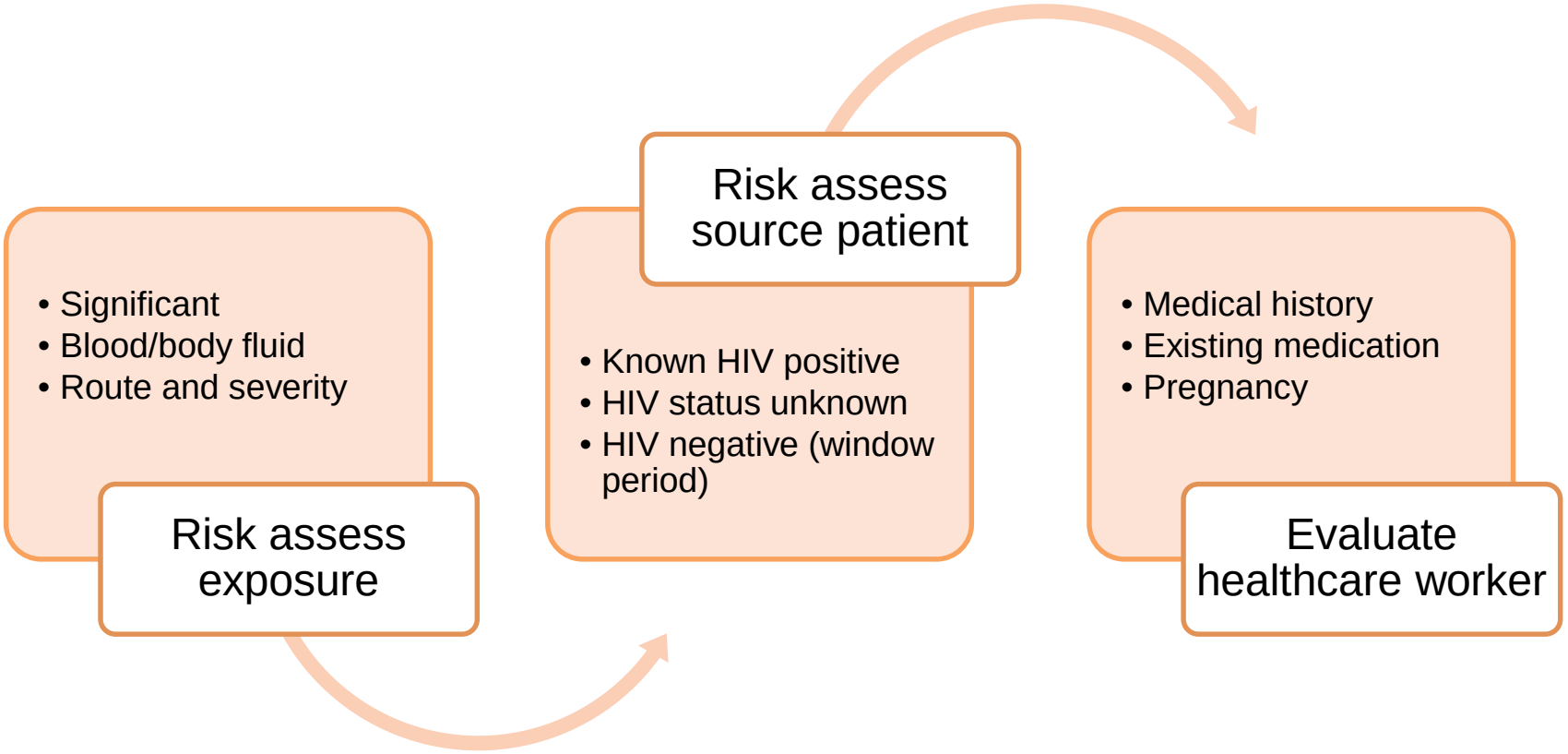
HIV post-exposure prophylaxis (PEP)



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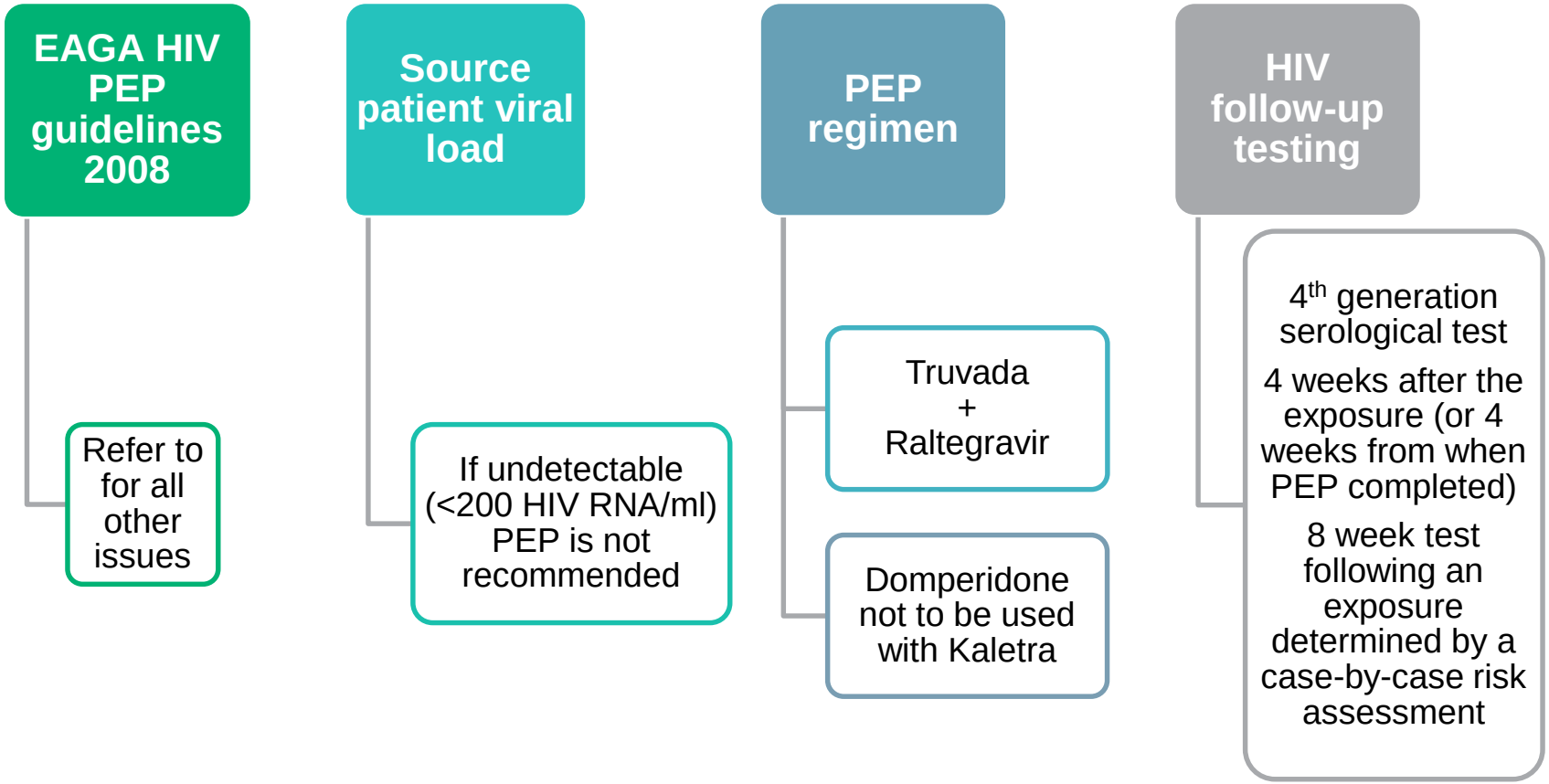
Changes to HIV PEP guidance (2013/14)



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Hepatitis C seroconversions

- 21 cases reported (17 from England and four from Scotland)

Of 20 cases where information available:

- All percutaneous exposures; majority injured by hollowbore needles
- Two-thirds (13) involved venepuncture and cannulation procedures
- Nearly half (9) exposures reported to have occurred after the procedure; most potentially preventable

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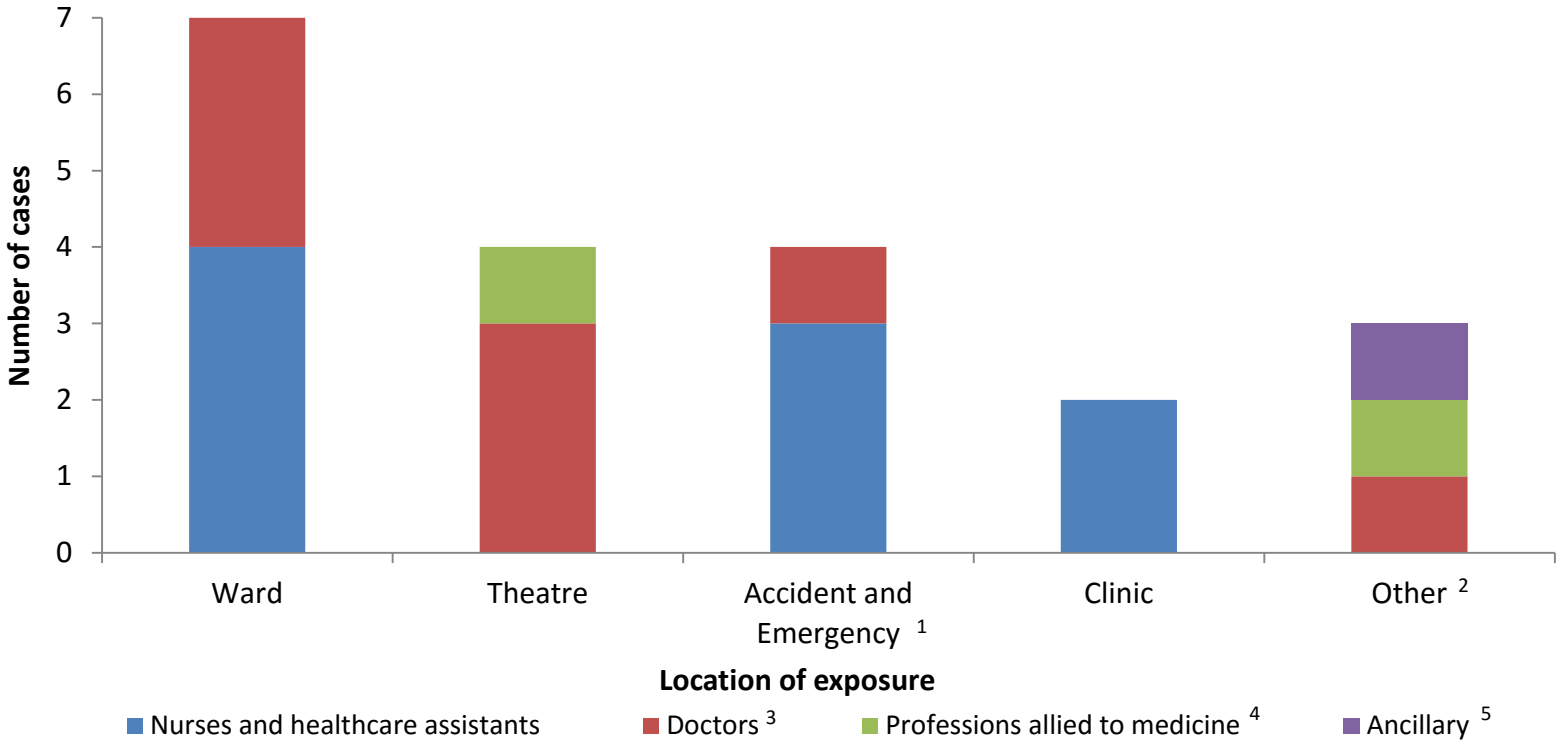
Hepatitis C seroconversions, by location of exposure and occupation, 1997-2013



[1] Includes a medical assessment unit.
[2] Other = phlebotomy department; GP surgery; dental surgery.
[3] Includes 1 dentist.
[4] Professions allied to medicine = phlebotomist; operating department assistant.
[5] Ancillary staff = housekeeping staff member.

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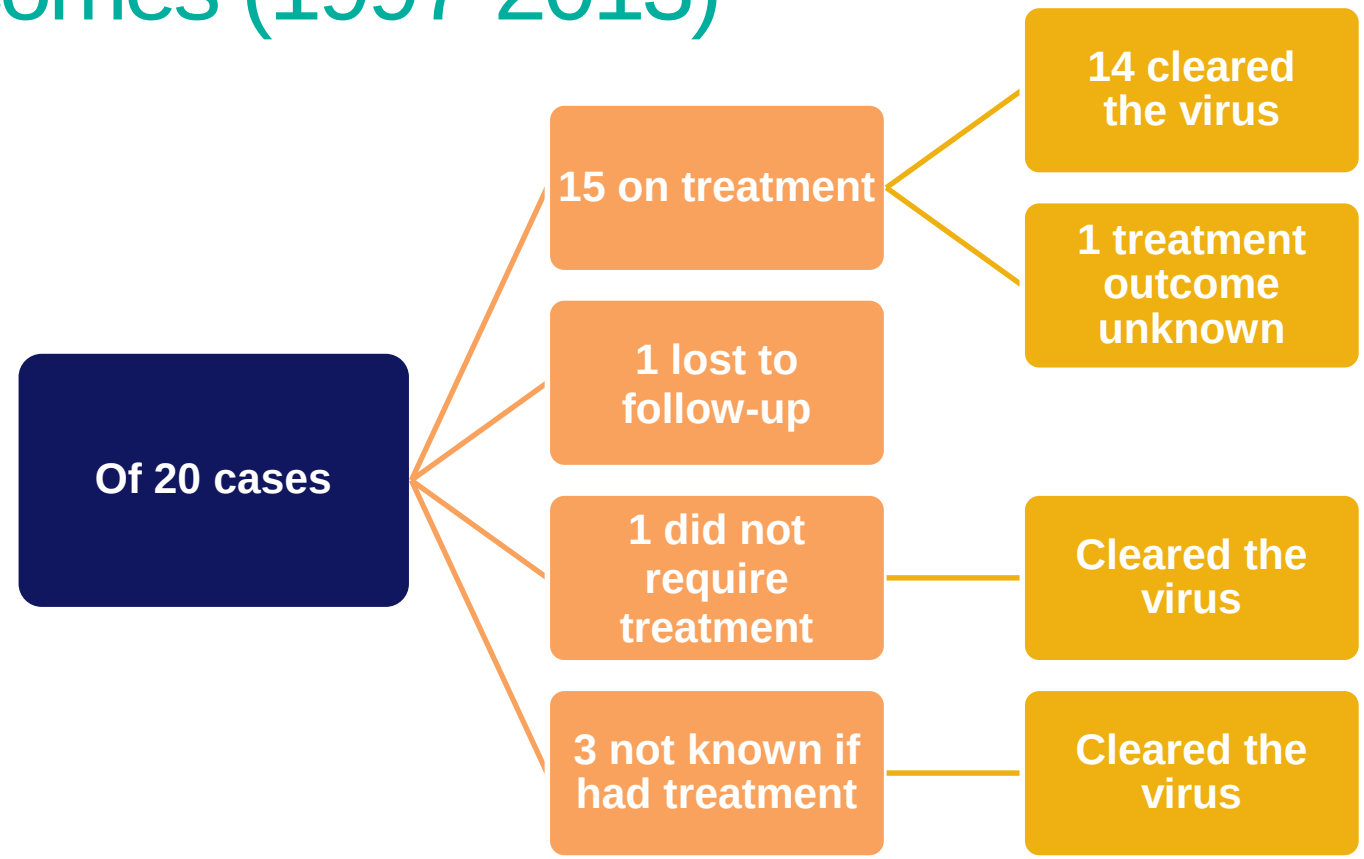
Overview of HCV seroconversion outcomes (1997-2013)



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Treatment of acute hepatitis C

Unresolved issues

- Application of virological markers and completeness of follow-up
- Is the evidence for early treatment of acute hepatitis C now sufficient?
- Which patients to treat, symptomatic *v* asymptomatic?
- Which treatment regimen, IFN or pegIFN alone or combination therapy with ribavirin?
- When should we be initiating treatment for healthcare workers who have seroconverted? Immediately or watchful waiting to allow spontaneous viral clearance?
- Should the same approach be applied to patients following iatrogenic or nosocomial transmissions?
- How long to treat for, 6 months or 1 year as for chronic hepatitis C?
- Hepatitis C viral load is high at seroconversion, what are the implications of this in healthcare worker to patient hepatitis C transmission? Should we be looking for possible cases of transmission as part of the post exposure management of the exposed and infected healthcare worker?

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UK policy: Hepatitis B infected healthcare workers

- In 1993, documented outbreaks of HBV in patients operated on by HBeAg +ve HCWs.
- DOH issued guidelines restricting all HBeAg +ve HCWs from performing EPPs.
- Despite these guidelines, further cases of HBV transmission were reported from HCWs shown to be HBeAg negative, **but with high HBV DNA levels**
- In June 2000 further guidelines were issued.
- Restrictions extended from HBeAg positive HCW, to all HBeAg -ve HCWs with HBV DNA above 10^3 genome equivalents/ml.
- The practice of HCWs with levels below 10^3, was not restricted.
- HCW whose HBV DNA was above 10^3 genome equivalents/ml, had to stop performing EPPs.

UK Health Department. Health Service Circular HSC 2000/020: Hepatitis B infected health care workers. June 2000.
UK Health Department. Health Service Guidelines HSG(93)40: Protecting health care workers and patients from hepatitis B. August 1993

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UK policy: Hepatitis B infected healthcare workers and antiviral therapy, March 2007

- HBV infected HCWs, HBeAg-ve with pre-treatment HBV DNA between 10^3 and 10^5geq/ml allowed to perform EPPs on oral antiviral therapy if viral load suppressed to $<10^3$ geq/ml on two consecutive tests, no less than one month apart.
- HCWs to have regular monitoring of HBV DNA levels every 3 months from date of previous sample using an IVS in OHD.
- Samples to go to two designated laboratories.
- If HBV DNA goes above 10^3 geq/ml, eg breakthrough infections, restriction of EPP practice.
- Stop treatment HCWs under ethical obligation to ceases EPP work.

Department of Health, Hepatitis B infected healthcare workers and antiviral therapy. March 2007

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UK policy: Hepatitis B infected healthcare workers and antiviral therapy, March 2007

Rationale for restriction in levels >10^5 geq/ml

- HCWs with HBV DNA levels above 10^5 geq/ml restricted from EPPs while taking antiviral therapy on grounds of patient safety.
- With HBV DNA levels between 10^3 and 10^5 geq/ml, viral replication should be suppressed to levels where risk of emergency of drug resistance is likely to be low.
- If resistant strains occurred, HBV DNA levels should not rise above the baseline and changes should be picked up with frequent monitoring.
- Baseline >10^5, emergency of resistant strains has a risk of levels returning to levels where transmissions have occurred.

Department of Health, Hepatitis B infected healthcare workers and antiviral therapy. March 2007

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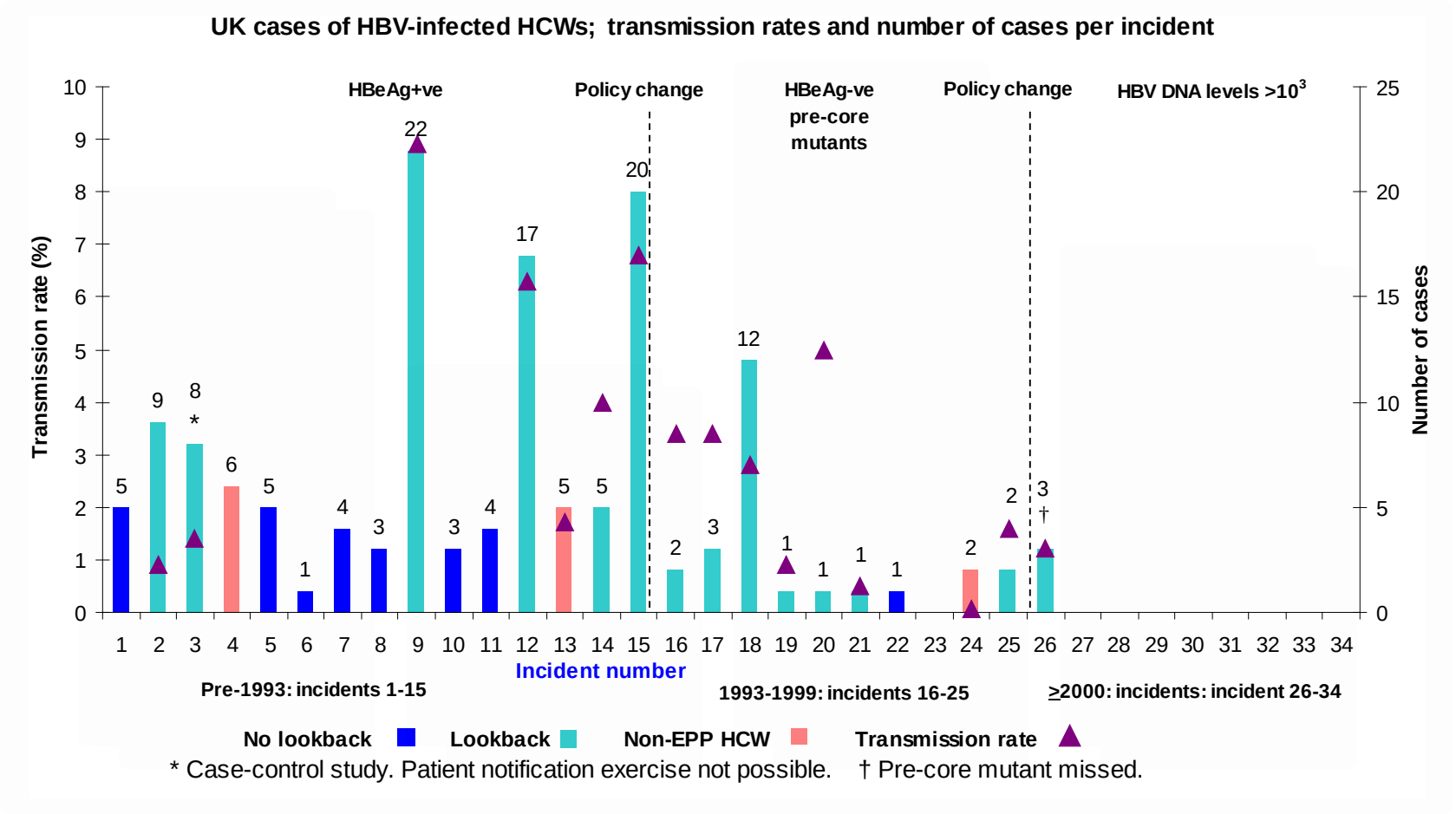
HBV infected HCWs



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HBV vaccine and boosting

Eike Leuridan and Pierre Van Damme. Hepatitis B and the need for a Booster Dose; Clin. Infect.Dis: 2011; 53 (1): 68-75

- Anamnestic response
- Infection rate in vaccinated populations
- Invitro B and T cell activity
- Seroepidemiological studies

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UK policy: Hepatitis C infected healthcare workers

Status	Action
HCW who know they are infected with HCV (e.g. who have antibodies to HCV) and who carry out EPPs	HCV RNA test • If positive, should not perform EPPs
HCWs who suspect that they may have been exposed to HCV infection e.g. unscreened blood/untreated plasma products; sharing of injecting equipment whilst misusing drugs; significant occupational exposures; involvement as HCW or patient in invasive procedures in parts of the world where inadequate infection control/high HCV prevalence	HCV antibody screening • If positive, and HCV RNA detected, should not perform EPPs
HCWs intending to begin professional training for a career that relies upon the performance of EPPs e.g. surgical specialty SHOs, dental students, nurse & midwifery trainees, ambulance staff, podiatric surgery trainees	HCV antibody screening • If positive, and HCV RNA detected, exclude from training* * Midwifery students only allowed to proceed with training on the understanding they will not be able to perform EPPs, and hence not be able to undertake the full ranges of activities in the specialty.

Source: Department of Health, Hepatitis C infected health care workers. August 2002

Total Hepatitis C UKAP Referrals 2002 - 2016

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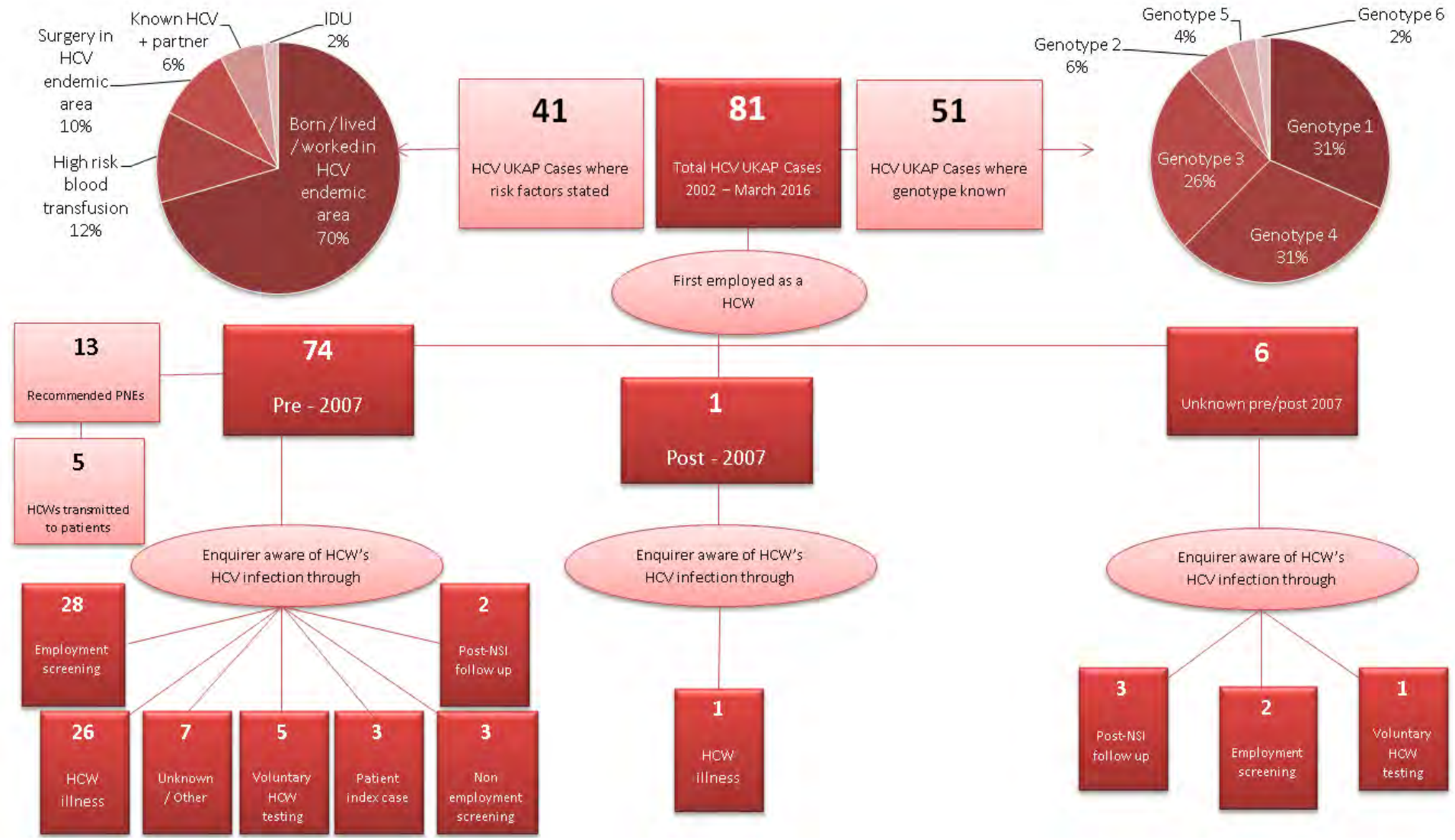

General Surgery and Obs. & Gyn. Hepatitis C UKAP Referrals 2002 - 2016

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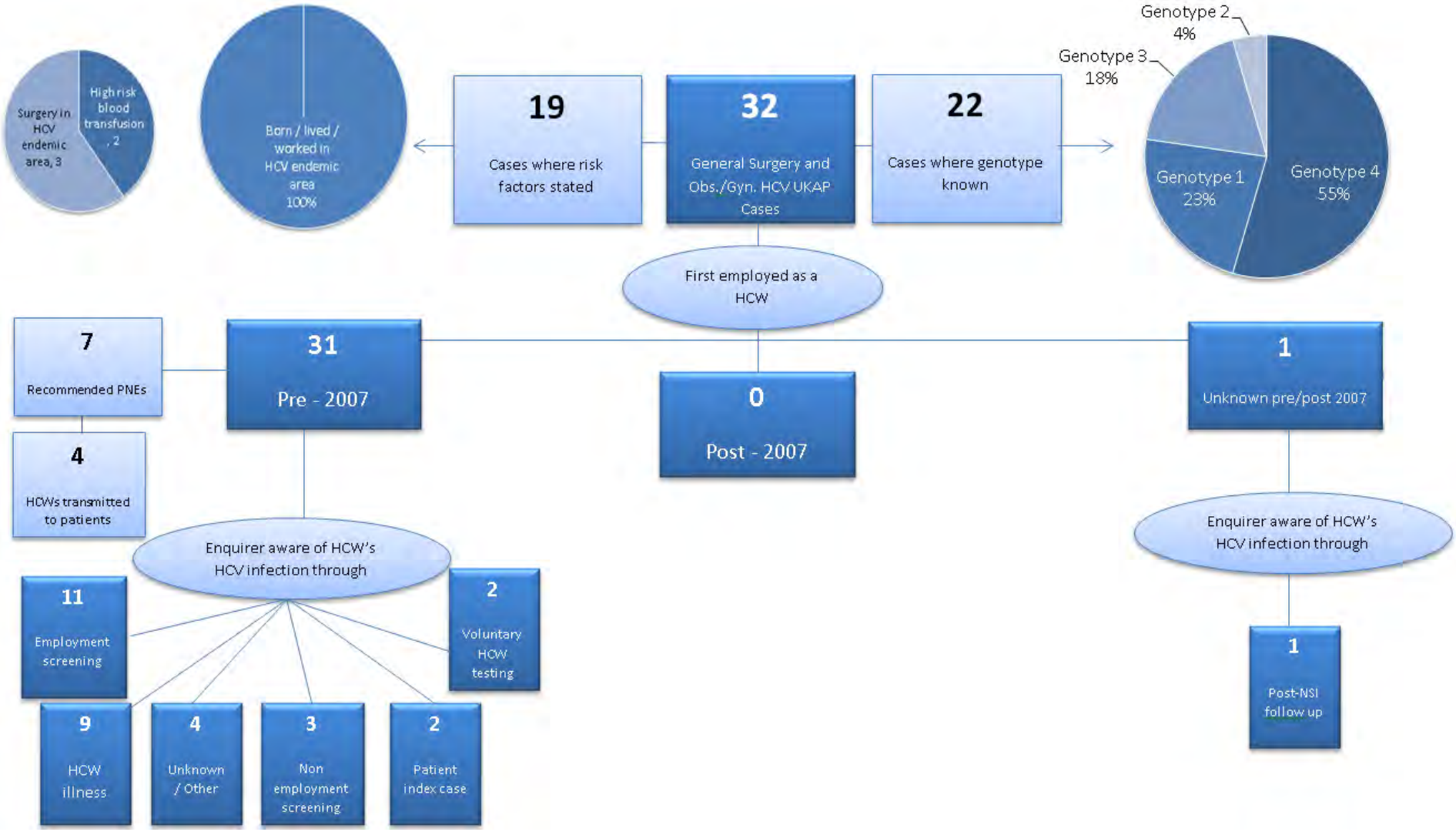

Ob & Gynae. Hepatitis C UKAP Referrals 2002 - 2016

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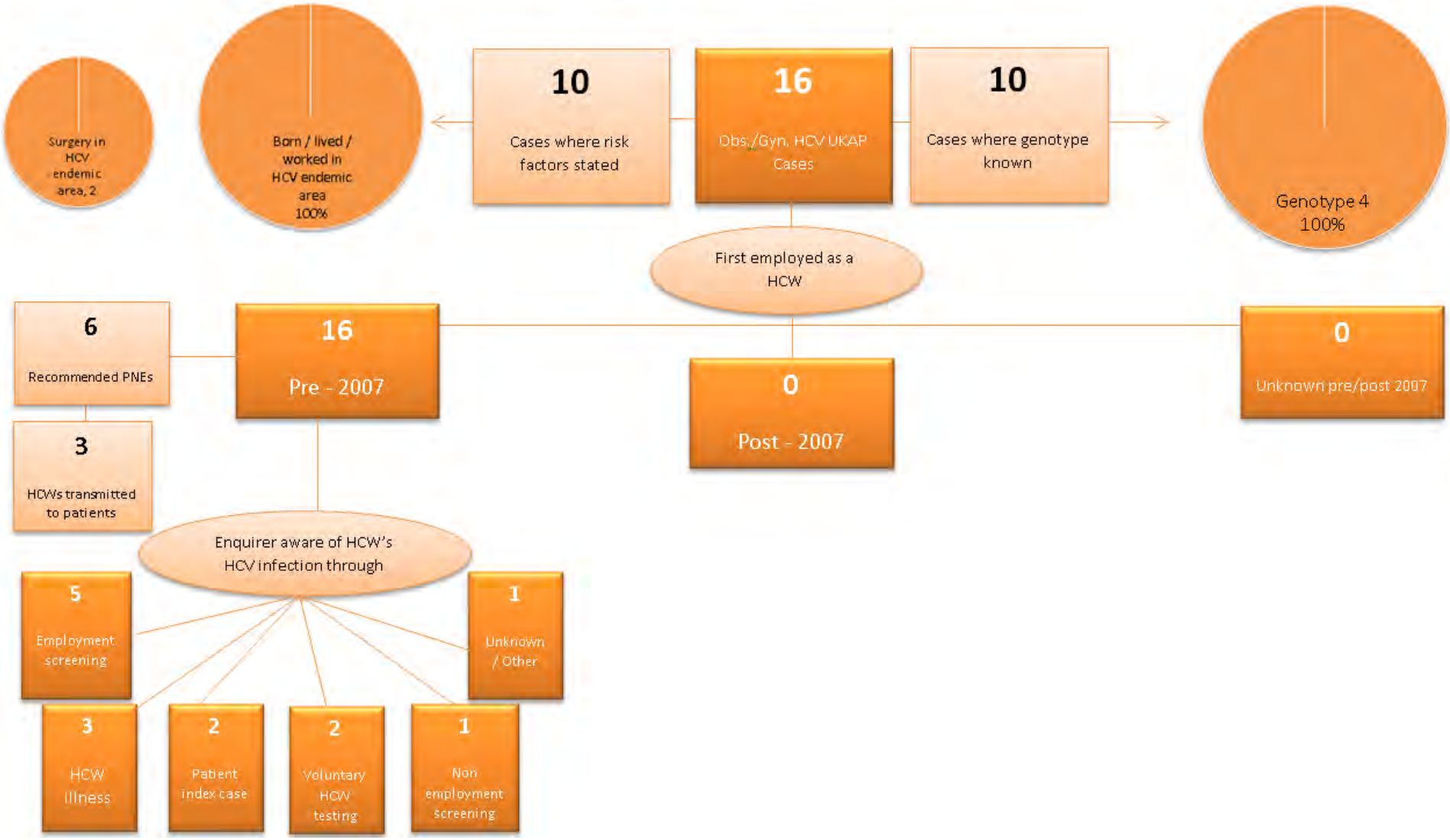

General Surgery Hepatitis C UKAP Referrals 2002 - 2016

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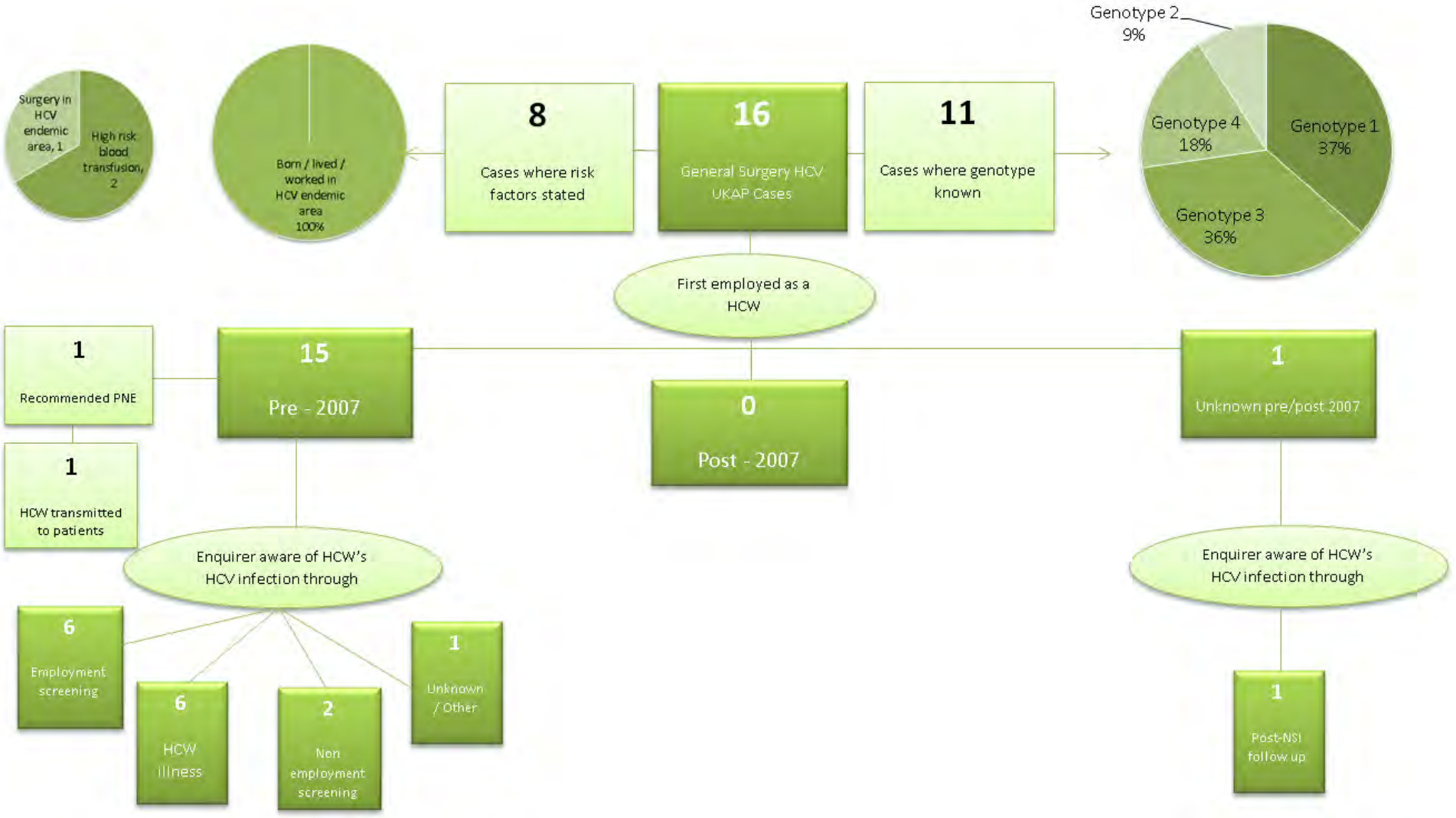

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UKAP Summary findings

- In the UK, 25 of the 32 documented cases in obstetrics and gynaecology and higher risk surgical specialities (i.e. general, cardiothoracic and vascular surgery) were found through incidental findings (e.g. screening, HCW illness, voluntary testing etc.)
- All HCWs were employed in the NHS pre-2007.
- No documented evidence of transmission since 2007.
- Since health clearance guidance was introduced in March 2007, employment screening has diagnosed 16 HCWs, 14 of which were known to be first employed within the NHS before 2007 (2 unknown occupational history).
- Many employers going beyond policy, testing existing EPP HCWs
- The estimated number of undiagnosed HCV infected EPP HCWs employed pre 2007 considered likely to be low

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Summary of current knowledge

- Data from UK patient notification exercises suggest the risk of transmission is low, less than 1 in 1000 in Obs & Gyn and General surgery.
- Pre-employment health clearance of EPP HCWs new to the NHS is a public health benefit in eliminating BBV infected HCWs
- It does not totally eliminated the risk of transmission to patients, recognises risk from historically infected HCWs may come to light.

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