ISOSS produces aggregated data tables on antiretroviral exposure and congenital anomalies in the UK on an annual basis for the APR. Individual prospective reports should also be sent to the APR antenatally with postnatal follow-up (forms are available at www.apregistry.com).

8.1.3 Individualised and person-centred care

The choice of therapy should always be discussed in full with every person and be individualised, taking into account the individual's concerns and preferences as well as the evidence base, to foster shared decision-making [15].

8.1.4 Anchor drugs with limited data

If women/people conceive on a regimen including agents with limited pharmacokinetic data such as bictegravir or doravirine, they should be counselled regarding the limited available evidence for its use in pregnancy compared to the regimens recommended in these guidelines and offered a third agent with more robust pharmacokinetic and safety data (see Section 8.2.2). Where uncertainty concerning these risks is acceptable and strong preference is given to continuation of the current non-recommended regimen (see recommendations in Sections 8.2 and 8.3 below), an individual should be supported with additional viral load monitoring every 1 to 2 months with or without TDM, as appropriate. At the time of writing, there remains insufficient evidence to support the continuation of injectable ART or regimens containing the drugs listed in Table 8.2.

8.1.5 Viral load monitoring after switching

Switches in ART should be closely monitored with viral load measurement at 2 weeks post-switch and, if the viral load remains undetectable, every 2 months thereafter (see Section 8.5).

8.2 ART dosing in pregnancy

Recommendations

- We do not recommend routine dose alterations for antiretrovirals during pregnancy if used at standard adult licensed doses with the following exceptions (Grade 1C):
  - Darunavir/ritonavir should be administered as 600 mg/100 mg twice daily if initiated in pregnancy; once-daily dosing can be continued if the woman/person conceived on darunavir/ritonavir and remains virologically suppressed;
  - Raltegravir should be administered as 400 mg twice daily if initiated or continued in pregnancy.
- We suggest that switching to standard dosing throughout pregnancy or regular TDM should be considered if a woman/person continues an off-licence non-standard dosing regimen (Grade 2C).

Rationale

Physiological changes that occur even during the first trimester of pregnancy may affect the kinetics of drug absorption, distribution, metabolism and elimination, thereby affecting drug dosing [16]. In pregnancy, gastrointestinal pH is increased, transit time becomes prolonged, body water and fat increase, and there are accompanying increases in cardiac output, ventilation and hepatic and renal blood flow. Plasma protein concentrations decrease, notably albumin and α1 acid glycoprotein; renal sodium reabsorption increases and changes occur in the metabolic enzyme pathways in the liver, including changes in cytochrome P450. Therefore it is important that pharmacokinetic studies in