

2016 Donor Haemovigilance Case Validation Exercise

Proposed Answers

| Case # | Diagnosis | Severity | Imputability |
|--------|--|----------------------------------|---|
| 1 | A2.1 Nerve injury/irritation (≥ 12 mo, \downarrow QOL): (93%) | <u>71% Mod</u> , <u>23% Sev</u> | 90% Definite/Probable |
| 2 | A1.1 Haematoma (67%) versus A1.3 <u>delayed bleeding</u> (6%) | <u>17% Mild</u> , 71% Mod | 98% Definite/Probable |
| 3 | B.2 Vasovagal reactions, with LOC (96%) w/ complications, w/ injury, onsite | <u>71% Mod</u> , 12% Sev | 98% Definite/Probable |
| 4 | C.4 Infiltration related to apheresis (74%) | <u>33% Mild</u> , <u>62% Mod</u> | 100% Definite/Probable |
| 5 | A2.1 Nerve injury/irritation (D < 12 months) (43%) A1.1 Haematoma (72%), D1 Local allergic reaction (72%) | <u>75% Mild</u> , 25% Mod | 98% Definite/Probable |
| 6 | A2.1 Nerve injury/irritation (≥ 12 mo, \downarrow QOL): (80%) | <u>69% Mod</u> , <u>27% Sev</u> | 92% Definite/Probable |
| 7 | A3.1 Superficial Thrombophlebitis (80%) | 25% Mild, <u>71% Mod</u> | 94% Definite/Probable |
| 8 | A2.1 Nerve injury/irritation (≥ 12 mo, \downarrow 5% QOL): (70%) | <u>46% Mod</u> , <u>48% Sev</u> | 87% Definite/Probable |
| 9 | A4.3 Compartment syndrome (87%) | 13% Mod, <u>85% Sev</u> | 96% Definite/Probable |
| 10 | E.4 TIA (44%) OR E.5 Cerebrovascular accident (70%) | 10% Mod, <u>90% Sev</u> | 46% <u>Possible</u> , 30% <u>Unlikely</u> |
| 11 | B.2 Vasovagal reaction, with LOC (94%) w/ complications, w/o injury, onsite | 21% Mild, 71% Mod | 98% Definite/Probable |
| 12 | D.2 Generalised allergic reaction (74%) | 44% Mild, 52% Mod | 88% Definite/Probable |
| 13 | A1.1 Haematoma (94%) | 71% Mild, 29% Mod | 100% Definite/Probable |
| 14 | A3.2 Cellulitis (96%) | 31% Mild, 60% Mod | 75% Definite/Probable |
| 15 | B.1 Vasovagal reaction, no LOC (98%) w/o injury, offsite | 83% Mild, 17% Mod | 94% Definite/Probable |

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| 16 | Other, fall unrelated to donation (78%) | <u>46% Mod, 52% Sev</u> | 78% <u>Unlikely/Excluded</u> |
| 17 | A4.4 Brachial Artery Pseudoaneurysm (78%) | 24% Mod, <u>75% Sev</u> | 100% Definite/Probable |
| 18 | B.1 Vasovagal reaction, no LOC (98%) w/o injury, onsite | <u>100% Mild</u> | 96% Definite/Probable |
| 19 | C.1 Citrate reaction (100%) | <u>63% Mild, 37% Mod</u> | 96% Definite/Probable |
| 20 | A1.3 Delayed bleeding (56%) w/ haematoma (59%) & Arm pain (33%) | <u>48% Mild, 50% Mod</u> | 98% Definite/Probable |
| 21 | E.1 Other acute cardiac symptoms (72%) | <u>29% Mod, 67% Sev</u> | 62% Possible, 10% <u>Unlikely</u> |
| 22 | A2.1 Nerve injury/irr. (D < 12 months): (98%) A2.2 Other arm pain (2%) | <u>96% Mild, 2% Mod</u> | 100% Definite/Probable |
| 23 | A2.2 Other arm pain, injury of tendon (67%) | 33% Mild, <u>65% Mod</u> | 96% Definite/Probable |
| 24 | B.2 VVR, with LOC (74%) w/o complications, w/o injury, onsite | <u>69% Mild, 31% Mod</u> | 98% Definite/Probable |
| 25 | A1.3 Delayed bleeding (94%) w/ A1.1 haematoma (30%) | <u>63% Mild, 35% Mod</u> | 96% Definite/Probable |
| 26 | A4.1 (Deep) Venous thrombosis (85%) | 47% Mod, <u>43% Sev</u> | 76% Definite/Probable |
| 27 | A2.1 Nerve injury/irr. (≥12mo, ↓ QOL): (69%) | 55% Mod, <u>37% Sev</u> | 94% Definite/Probable |
| 28 | A4.2 Arteriovenous fistula (93%) due to arterial puncture (41%) | <u>15% Mod, 85% Sev</u> | 98% Definite/Probable |
| 29 | B.2 Vasovagal reactions, with LOC (37%) w/o complications, w/o injury, offsite | 21% Mod, <u>73% Sev</u> | 35% Definite/ <u>Probable</u> 40% Possible |
| 30 | A1.2 Arterial puncture (96%) | <u>88% Mild, 10% Mod</u> | 98% Definite/Probable |