## Haematology audit template

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| Date of completion | (To be inserted when completed) |
| Name of lead author/ participants | (To be inserted) |
| Specialty | Haematology |
| Title | **An audit of compliance with the British Society for Haematology guideline for****the laboratory diagnosis and monitoring of von Willebrand disease** |
| Background | The British Society for Haematology (BSH) has published guidance on the laboratory diagnosis and monitoring of von Willebrand disease (VWD).1 This audit will review compliance with some of the main recommendations made. |
| Aim & objectives | To review whether:   * individuals are undergoing appropriate laboratory investigations for disease diagnosis and monitoring * testing strategies are being implemented to further classify VWD in diagnosed individuals * genetic or genomic tests are being performed to complement or confirm a diagnosis * adequate laboratory tests are being performed to manage diagnosed individuals. |
| Standards & criteria | **Criteria range:** 100%, or if not achieved, there is documentation in the case notes that explains the variance.  **Sample handling and transportation**   * Whole blood samples for coagulation tests should be maintained at an ambient temperature of 18–25°C during both transport and storage prior to processing. * The time between sample collection and testing (or freezing) of citrated plasma for VWD assays should be <12 hours.   **Initial laboratory investigations**   * A full blood count (FBC; including mean platelet volume) with a blood film for platelet morphology should be performed on all individuals being investigated for VWD or acquired von Willebrand syndrome (AVWS). * Assays for prothrombin time (PT), activated partial thromboplastin time (APTT) and Clauss fibrinogen should be performed on all individuals being investigated for VWD/AVWS.   **Initial diagnostic tests for VWD/AVWS**   * Initial investigations for VWD or AVWS should measure factor VIII activity (FVIII:C) by either one-stage clotting assay (OSCA) or chromogenic substrate assay (CSA), VWF antigen (VWF:Ag), and VWF activity (by VWF:RCo, VWF:GPIbR or VWF:GPIbM). * Laboratories should calibrate assays using plasmas that are traceable to the international standard for FVIII:C and for VWF, and results should be reported in IU/dL. * Laboratories diagnosing type 3 VWD should verify that methods employed to measure VWF: Ag are demonstrably capable of measuring to levels <1 IU/dL.   **Additional investigations for VWD classification**   * Multimer analysis should only be performed in specialised haemostasis laboratories with experience of performing the analysis and interpretation of the results, and which participate in appropriate external quality assessment (EQA). * Individuals with a newly identified reduced FVIII:C/VWF:Ag ratio should undergo genetic testing for suspected type 2N VWD and/or haemophilia A. * Individuals with suspected type 2B VWD or platelet-type von Willebrand disease (PT-VWD) should undergo genetic testing. * Individuals with reduced VWF half-life to desmopressin (DDAVP) should undergo genetic testing for VWD-Vicenza.   **Genetic or genomic testing**   * Informed consent must be obtained prior to referral of an individual for genetic testing, including providing information regarding potential incidental findings. * Interpretive reports should follow American College of Medical Genetics and Genomics (ACMG) and Association for Clinical Genomic Science (ACGS) guidelines and variants described according to the Human Genome Variation Society (HGVS) nomenclature.   **Laboratory testing to guide management**   * For pregnant individuals with VWD, and to assess response to DDAVP, FVIII:C (by OSCA or CSA), VWF activity (by VWF:RCo or VWF:GPIbR or VWF:GPIbM) and VWF:Ag should be measured. * To assess response to VWF concentrate in individuals with VWD, FVIII:C (by OSCAor CSA), and VWF activity (by VWF:RCo, VWF:GPIbR or VWF:GPIbM) should be measured.   To exclude a diagnosis of type 3 or severe type 2 VWD in neonates or infants, FVIII:C (by OSCA or CSA), VWF activity (by VWF:RCo or VWF:GPIbR or VWF:GPIbM) and VWF:Ag should be measured. |
| Method | **Sample selection**  Consecutive patients with VWD seen as outpatients or inpatients in the preceding 3–6 months, up to a maximum of 50 patients  **Data to be collected on proforma (see below)** |
| Results | (To be completed by the author)  The results of this audit show the following compliance with the standards.   |  |  |  |  | | --- | --- | --- | --- | | **Investigation** | **No. audited** | **No. compliant** | **% compliance** | | **Sample handling and transportation** | | | | | Whole blood samples for coagulation tests were maintained at an ambient temperature of 18– 25°C during both transport and storage prior to processing |  |  |  | | The time between sample collection and testing (or freezing) of citrated plasma for VWD assays was <12 hours |  |  |  | | **Initial laboratory investigations** | | | | | An FBC (including mean platelet volume) with a blood film for platelet morphology was performed on all individuals being investigated for VWD/AVWS |  |  |  | | Assays for PT, APTT and Clauss fibrinogen were performed on all individuals being investigated for VWD/AVWS |  |  |  | | **Initial diagnostic tests for VWD/AVWS** | | | | | Initial investigations for VWD or AVWS measured FVIII:C, VWF:Ag, and VWF activity (by VWF:RCo, VWF:GPIbR or VWF:GPIbM) |  |  |  | | Laboratories calibrated assays using plasmas that were traceable to the international standard for FVIII:C and for VWF, and results were reported in IU/dL |  |  |  | | Laboratory methods measuring VWF:Ag to diagnose type 3 VWD, were demonstrably capable of measuring to levels <1 IU/dL |  |  |  | | **Additional investigations for VWD classification** | | | | | Multimer analysis was performed in a specialised haemostasis laboratory with experience of performing the analysis and interpretation of the results, and which participates in appropriate EQA |  |  |  | | Individuals with a newly identified reduced FVIII:C/VWF:Ag ratio have undergone genetic testing for suspected type 2N VWD/haemophilia A |  |  |  | | Individuals with suspected type 2B VWD or PT-VWD have undergone genetic testing |  |  |  | | Individuals with reduced VWF half-life to DDAVP have undergone genetic testing for VWD-Vicenza |  |  |  | | **Genetic or genomic testing** | | | | | Informed consent has been obtained prior to referral of an individual for genetic testing, including providing information regarding potential incidental findings |  |  |  | | Interpretive reports follow ACMG and ACGS guidelines and variants described according to the HGVS nomenclature |  |  |  | | **Laboratory testing to guide management** | | | | | For pregnant individuals with VWD, and to assess response to DDAVP, FVIII:C (by OSCA or CSA), VWF activity (by VWF:RCo or VWF:GPIbR or VWF:GPIbM) and VWF:Ag was measured |  |  |  | | To assess response to VWF concentrate in individuals with VWD, FVIII:C (by OSCAor CSA), and VWF activity (by VWF:RCo, VWF:GPIbR or VWF:GPIbM) was measured |  |  |  | | To exclude a diagnosis of type 3 or severe type 2 VWD in neonates or infants, FVIII:C (by OSCA or CSA), VWF activity (by VWF:RCo or VWF:GPIbR or VWF:GPIbM) and VWF:Ag was measured |  |  |  |   **Commentary:** |
| Conclusion | (To be completed by the author) |
| Recommend- ations for improvement | Present the result with recommendations, actions, and responsibilities for action and a timescale for implementation. Assign a person(s) responsible to do the work within a time frame.  Some suggestions:   * Highlight areas of practice that are different * Present findings |
| Action plan | (To be completed by the author – see attached action plan proforma) |
| Re-audit date | (To be completed by the author) |
| References | 1. Platton S, Baker P, Bowyer A, Keenan C, Lawrence C, Lester W *et al*. Guideline for laboratory diagnosis and monitoring of von Willebrand disease: A joint guideline from the United Kingdom Haemophilia Centre Doctors' Organisation and the British Society for Haematology. *Br J Haematol* 2024;204:1714–1731. |

## Data collection proforma the laboratory diagnosis and monitoring of von Willebrand disease

## Audit reviewing practice

Patient name:

Hospital number:

Date of birth:

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| Standard | | 1Yes | 2No | | 3 If shaded box not ticked, was there documentation to explain the variance? Yes/No plus free-text comment | | | 4 Compliant with guideline if shaded box ticked or an appropriate explanation from column 3. Yes/No (Record if standard not applicable) |
| **Sample handling and transportation** | | | | | | | | |
| **1**Whole blood samples for coagulation tests were maintained at an ambient temperature of 18–25°C during both transport and storage prior to processing |  | | |  | |  |  | |
| **2**The time between sample collection and testing (or freezing) of citrated plasma for VWD assays was <12 hours |  | | |  | |  |  | |
| **Initial laboratory investigations** | | | | | | | | |
| **1**An FBC (including mean platelet volume) with a blood film for platelet morphology was performed on all individuals being investigated for VWD/AVWS |  | | |  | |  |  | |
| **2**Assays for PT, APTT and Clauss fibrinogen, were performed on all individuals being investigated for VWD/AVWS |  | | |  | |  |  | |
| **Initial diagnostic tests for VWD/AVWS** | | | | | | | | |
| **1**Initial investigations for VWD or AVWS measured FVIII:C (by OSCA or CSA), VWF antigen, and VWF activity (by VWF:RCo, VWF:GPIbR or VWF:GPIbM) |  | | |  | |  |  | |
| **2**Laboratories calibrated assays using plasmas that are traceable to the international standard for FVIII:C and for VWF, and results were reported in IU/dL |  | | |  | |  |  | |
| **3**Laboratory methods measuring VWF:Ag to diagnose type 3 VWD, were demonstrably capable of measuring to levels <1 IU/dL |  | | |  | |  |  | |
| **Additional investigations for VWD classification** | | | | | | | | |
| **1**Multimer analysis was performed in a specialised haemostasis laboratory with experience of performing the analysis and interpretation of the results, and which participates in appropriate EQA |  | | |  | |  |  | |
| **2**Individuals with a newly identified reduced FVIII:C/VWF:Ag ratio have undergone genetic testing for suspected type 2N VWD/haemophilia A |  | | |  | |  |  | |
| **3**Individuals with suspected type 2B VWD or PT-VWD have undergone genetic testing |  | | |  | |  |  | |
| **4**Individuals with reduced VWF half-life to DDAVP have undergone genetic testing for VWD-Vicenza |  | | |  | |  |  | |
| **Genetic or genomic testing** | | | | | | | | |
| **1**Informed consent has been obtained prior to referral of an individual for genetic testing, including providing information regarding potential incidental findings |  | | |  | |  |  | |
| **2**Interpretive reports follow ACMG and ACGS guidelines and variants described according to the HGVS nomenclature |  | | |  | |  |  | |
| **Laboratory testing to guide management** | | | | | | | | |
| **1**For pregnant individuals with VWD, and to assess response to DDAVP, FVIII:C (by OSCA or CSA), VWF activity (by VWF:RCo or VWF:GPIbR or VWF:GPIbM) and VWF:Ag was measured |  | | |  | |  |  | |
| **2**To assess response to VWF concentrate in individuals with VWD, FVIII:C (by OSCAor CSA), and VWF activity (by VWF:RCo, VWF:GPIbR or VWF:GPIbM) was measured |  | | |  | |  |  | |
| **3**To exclude a diagnosis of type 3 or severe type 2 VWD in neonates or infants, FVIII:C (by OSCA or CSA), VWF activity (by VWF:RCo or VWF:GPIbR or VWF:GPIbM) and VWF:Ag was measured |  | | |  | |  |  | |

**List of investigations**

(To be completed by the author)

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|  | **Yes** | **No** |
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| **Audit action plan**  An audit of compliance with the BSH guideline for the laboratory diagnosis and monitoring of von Willebrand disease | | | | | | |
| Audit recommendation | Objective | Action | Timescale | Barriers and constraints | Outcome | Monitoring |
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