## 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 diagnosis and management of smouldering myeloma** |
| Background | The British Society for Haematology (BSH) has published guidance on the diagnosis and management of smouldering myeloma.1–3 This audit will review compliance with some of the main recommendations made. |
| Aim & objectives | To review whether:   * investigations are being performed to confirm the diagnosis of smouldering myeloma and to estimate the tumour burden and prognosis * newly diagnosed patients have been risk stratified * supportive care is being provided to patients in the form of psychological support, vaccinations and COVID-19 infection treatment * appropriate and adequate disease monitoring is being performed. |
| Standards & criteria | **Criteria range:** 100%, or if not achieved, there is documentation in the case notes that explains the variance.  **Investigations for patients with suspected and confirmed myeloma**   * The following should be screened: * full blood count (FBC) * urea and creatinine * calcium * immunoglobulins and serum electrophoresis * immunofixation of serum * serum-free light chains (SFLC) to investigate monoclonal light chains. * The following diagnostic tests should be performed: * bone marrow aspirate and trephine biopsy with plasma cell phenotyping. Image to assess bone disease, using the following, in order of preference: diffusion-weighted whole-body (WB) magnetic resonance imaging (MRI), positron emission tomography (PET)-computed tomography (CT) or low-dose WB-CT. * The following tests should be performed to estimate tumour burden and prognosis: * interphase fluorescent in situ hybridisation (FISH) analyses on bone marrow samples on CD138-selected cells for: t(4;14) (p16;q32), t(14;16) (q32;q23), t(11;14) (q13;q32), 17p-,1q+, 1p- * β2 microglobulin * lactate dehydrogenase (LDH) * albumin. * Renal biopsy should be performed if myeloma is the suspected cause of renal impairment and SFLC <500 mg/L. * Discuss all cases of newly diagnosed myeloma at a multi-disciplinary team (MDT) meeting.   **Risk stratification**   * Newly diagnosed patients should be risk stratified using the Mayo 20-2-20 (2018) risk model (Mateos *et al.*, 2020) or the updated International Myeloma Working Group (IMWG) model 20-2-20 with FISH incorporated (2020; Lakshman *et al*., 2018) to guide further management. * Patients with evolving disease should be restaged. * **Supportive care** * Provide patients with clear information and refer for psychological support where necessary. * Offer patients (non-live) pneumococcal vaccination at diagnosis; Prevenar13 should administered followed by Pneumovax23 2 months later. Vaccination should be repeated every 5 years. * 6 weeks after Pneumovax23, functional antibodies should be checked in patients with a history of recurrent or serious infection. * Vaccinate patients over 50 years of age against shingles with a 2-dose schedule of recombinant zoster vaccine (Shingrix) 8 weeks to 6 months apart (United Kingdom Department of Health guidance; UK DoH). * The annual flu vaccination should be administered for patients and household members. * The COVID-19 vaccination should be administered to patients and household members (UK DoH guidance). * Provide anti-COVID treatment for COVID-19-positive patients within 5 days of symptom onset   **Monitoring disease**   * Low-risk (Mayo [20-2-20]/IMWG) patients should be monitored every 3 months for 1 year (if stable extend to 1–2 times per year); intermediate-risk patients should be monitored every 3 months for 1–2 years (if stable extend to every 4– 6 months); and high-risk patients should be monitored every 3 months for 5 years, and if available, entered into an appropriate clinical trial. * Imaging should be repeated annually for high-risk patients with a low threshold. (particularly those with evolving disease markers). * Patients with equivocal or solitary focal lesions at baseline should have interval imaging every 3–6 months.   Patients should be monitored as high risk, where evolving biochemical markers are present (anaemia and paraprotein), or there is an increase in the Mayo 20-2-20 or IMWG risk group within the first 5 years of diagnosis.  Stratified clinical models should be used for long-term monitoring in either primary or secondary care settings and should be overseen by adequately trained healthcare professionals. |
| Method | **Sample selection**  Up to 20 patients diagnosed with smouldering myeloma.  **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.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **No. audited** | **No. compliant** | **% compliance** | | | **Investigations** | | | | | | Patients were screened for:   * full blood count * urea and creatinine levels * calcium levels * immunoglobulin and serum electrophoresis * immunofixation of serum * serum-free light chain analysis. |  |  |  | | | The following diagnostic tests were performed:   * bone marrow aspirate and trephine biopsy taken, and plasma cells phenotyped * bone disease assessment using cross-sectional imaging (WB-MRI, PET-CT or low-dose WB-CT). |  |  |  | | | Tests to estimate tumour burden and prognosis were carried out as follows:   * interphase FISH analyses on bone marrow samples on CD138-selected cells for: t(4;14) (p16;q32), t(14;16) (q32;q23), t(11;14) (q13;q32), 17p-, 1q+, 1p- * β2 microglobulin * lactate dehydrogenase * albumin. |  |  |  | | | Renal biopsy was performed in patients where myeloma was the suspected cause of renal impairment and SFLC <500 mg/L |  |  |  | | | Newly diagnosed cases of myeloma were discussed at an MDT meeting |  |  |  | | | **Risk stratification** | | | | | | Newly diagnosed patients were risk stratified using the Mayo 20-2-20 (2018) risk model or the updated IMWG model 20-2-20 with FISH incorporated (2020) |  |  |  | | | Patients with evolving disease were restaged |  |  |  | | | **Supportive care** | | | | | | Patients were provided with clear information and referred for psychological support if required |  |  |  | | | Patients were vaccinated with Prevenar13 followed by Pneumovax23 2 months later |  |  |  | | | In patients with a history of recurrent or serious infection, functional antibodies were checked 6 weeks after Pneumovax23 vaccination |  |  |  | | | In patients over 50 years of age, vaccination was administered against shingles, with a two-dose schedule of Shingrix 8 weeks to 6 months apart |  |  |  | | | The annual flu vaccination was administered to patients and household members |  |  |  | | | The COVID-19 vaccination was administered to patients and household members |  |  |  | | | In COVID-19-positive patients, anti-COVID treatment was administered within 5 days of symptom onset |  |  |  | | | **Monitoring disease** | | | | | | Low risk (Mayo [20-2-20]/IMWG) patients were monitored every 3 months for 1 year (if stable, this extended to 1–2 times per year) |  |  |  | | | Intermediate-risk patients were monitored every 3 months for 1–2 years (if stable, this was extended to every 4–6 months) |  |  |  | | | High-risk patients were monitored every 3 months for 5 years, or if available, entered into a clinical trial |  |  |  | | | Annual imaging repeats have been carried out for high-risk patients with a low threshold (particularly those with evolving disease markers) |  |  |  | | | Patients with equivocal or solitary focal lesions at baseline underwent interval imaging every 3–6 months |  |  |  | | | Patients were monitored as high risk when evolving biochemical markers were present (anaemia and paraprotein), or there was an increase in the Mayo 20-2-20 or IMWG risk group within the first 5 years of diagnosis |  |  |  | | | Stratified clinical models were used for long-term monitoring in either primary or secondary care settings, overseen by adequately trained healthcare professionals |  |  |  |   **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 timeframe. |
| Action plan | (To be completed by the author – see attached action plan proforma) |
| Re-audit date | (To be completed by the author) |
| References | 1. Hughes D, Yong K, Ramasamy K, Stern S, Boyle E, Ashcroft J *et al*. Diagnosis and management of smouldering myeloma: A British Society for Haematology Good Practice Paper. *Br J Haematol* 2024;204:1193–1206. 2. Mateos MV, Kumar S, Dimopoulos MA, González-Calle V, Kastritis E, Hajek R *et al*. International Myeloma Working Group risk stratification model for smoldering multiple myeloma (SMM). *Blood Cancer J* 2020;10:102. 3. Lakshman A, Rajkumar SV, Buadi FK, Binder M, Gertz MA, Lacy MQ *et al*. Risk stratification of smoldering multiple myeloma incorporating revised IMWG diagnostic criteria. *Blood Cancer J* 2018;8:59. |

## Data collection proforma for the diagnosis and management of patients with smouldering myeloma

## 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) | | |
| **Diagnostic investigations** | | | | | | | | |
| **1**The following screening tests were performed:   * full blood count * urea and creatinine levels * calcium levels * immunoglobulin and serum electrophoresis * immunofixation of serum * serum-free light chain analysis |  |  | |  | |  | |
| **2**Diagnostic tests were carried out:   * bone marrow aspirate and trephine biopsy taken, and plasma cells phenotyped * bone disease assessment using cross-sectional imaging (WB-MRI, PET- CT or low-dose WB- CT) |  |  | |  | |  | |
| **3**Tests to estimate tumour burden and prognosis were carried out:   * interphase FISH analyses on bone marrow samples on CD138-selected cells for: t(4;14) (p16;q32), t(14;16) (q32;q23), t(11;14) (q13;q32), 17p-, 1q+, 1p- * β2 microglobulin * lactate dehydrogenase * albumin |  |  | |  | |  | |
| **4**Renal biopsy was performed in patients where myeloma is the suspected cause of renal impairment and SFLC <500 mg/L |  |  | |  | |  | |
| **5**Newly diagnosed cases of myeloma were discussed at an MDT meeting |  |  | |  | |  | |
| **Risk stratification** | | | | | | | |
| **1**Newly diagnosed patients were risk stratified using the Mayo 20-2-20 (2018) risk model or the updated IMWG model 20-2-20 with FISH incorporated (2020) |  |  | |  | |  | |
| **2**Patients with evolving disease were restaged |  |  | |  | |  | |
| **Supportive care** | | | | | | | |
| **1**Patients were provided with clear information and referred for psychological support if required |  |  | |  | |  | |
| **2**Patients were vaccinated with Prevenar13, followed by Pneumovax23 2 months later |  |  | |  | |  | |
| **3**In patients with a history of recurrent or serious infection, functional antibodies were checked 6 weeks after Pneumovax23 vaccination |  |  | |  | |  | |
| **4**In patients over 50 years of age, vaccination was administered against shingles, with a 2-dose schedule of Shingrix 8 weeks to 6 months apart |  |  | |  | |  | |
| **5**The annual flu vaccination was administered to patients and household members |  |  | |  | |  | |
| **6**The COVID-19 vaccination was administered to patients and household members |  |  | |  | |  | |
| **7**In COVID-19 positive patients, anti-COVID treatment was administered within 5 days of symptom onset |  |  | |  | |  | |
| **Monitoring disease** | | | | | | | |
| **1**Low risk (Mayo [20- 2- 20]/IMWG) patients were monitored every 3 months for 1 year (if stable, this extended to 1– 2 times per year) |  |  | |  | |  | |
| **2**Intermediate-risk patients were monitored every 3 months for 1–2 years (if stable, this was extended to 4–6 monthly) |  |  | |  | |  | |
| **3**High-risk patients were monitored every 3 months for 5 years, or if available, entered into a clinical trial |  |  | |  | |  | |
| **4**Annual imaging repeats have been performed in high-risk patients with a low threshold (particularly those with evolving disease markers) |  |  | |  | |  | |
| **5**Patients with equivocal or solitary focal lesions at baseline underwent interval imaging every 3–6 months |  |  | |  | |  | |
| **6**Patients were monitored as high risk when evolving biochemical markers were present (anaemia and paraprotein), or there was an increase in the Mayo 20-2-20 or IMWG risk group within the first 5 years of diagnosis |  |  | |  | |  | |
| **7**Stratified clinical models were used for long-term monitoring in either primary or secondary care settings, overseen by adequately trained healthcare professionals |  |  | |  | |  | |

**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 diagnosis and management of patients with smouldering myeloma | | | | | | |
| Audit recommendation | Objective | Action | Timescale | Barriers and constraints | Outcome | Monitoring |
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