# What patient assessment skills do pharmacist independent prescribers require to prescribe immunomodulators in myeloma?

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**Abstract**

Aim

To gain consensus on the patient assessment skills (PAS) required by pharmacist independent prescribers (PIPs) prescribing immunomodulators (IMIDs) in myeloma across National Health Service Scotland.

Methods

This was a two-phase study which used nominal group technique (NGT) to gain local consensus followed by a two-round eDelphi questionnaire to gain national consensus across all cancer networks.

Setting

This project was conducted across the three cancer networks within NHS Scotland: South East Scotland Cancer Network (SCAN); West of Scotland Cancer Network (WoSCAN) and North Cancer Alliance (NCA).

Subjects

Participants were invited from each cancer network (SCAN, WoSCAN and NCA) and included haematology consultants, haematology specialist registrars, haematology advanced nurse practitioners and haematology pharmacists.

Results

There were five participants in the NGT. Twenty-two out of 31 PAS gained local consensus, seven PAS did not gain consensus and two PAS were deemed irrelevant. There were 12 and 14 participants in round one and two of the eDelphi questionnaire, respectively. Twenty-nine PAS were included in the first-round questionnaire and 21 gained consensus. The remaining eight PAS were included in round two where seven did not achieve consensus and one achieved disagreement consensus.

Conclusion

This research outlines 21 PAS required for PIPs to prescribe IMIDs for myeloma patients according to haematology specialists in Scotland. Discussion on PAS without consensus showed that the PIPs would have a shared responsibility with the consultant. This work should inform the development of a competency framework to allow training of PIPs in Scotland. Some PAS could be transferrable for PIPs prescribing SACT for other haematological malignancies.

## Introduction

The Scottish Medicines Consortium has recently approved lenalidomide (a type of immunomodulator (IMID) which is a systemic anti-cancer therapy (SACT)) for use in Scotland for the maintenance of multiple myeloma in patients who have undergone autologous stem cell transplantation(ASCT)[1].. This is a new group of patients who have not been treated previously with lenalidomide and therefore more prescribing resources are required to support this patient group. Myeloma affects 24,000 people in the UK at any one time[2]. There are approximately 5,800 new patients diagnosed each year in the UK. In Scotland the incidence was 457 cases in 2017[3]. According to the Myeloma XI trial 45% of patients newly diagnosed myeloma will be eligible for maintenance treatment after ASCT[4]. Incidence is set to rise over the next decade due to an ageing population. The increase in patient numbers will have practical service implications and the current prescribing resource will be unable to absorb this increased demand. New treatments offering improved survival outcomes are also becoming available each year, therefore, services must increase the amount of SACT prescribers for myeloma patients to manage this increasing number of patients. The evolving myeloma treatment landscape offers a prime opportunity for PIPs to upskill and provide essential prescribing resource. Although PIPs may be qualified to prescribe, clarification is required on what patient assessment skills (PAS) and associated training would be needed to gain competence in prescribing IMIDs. Due to local service pressures in the South East Scotland Cancer Network (SCAN), it was decided that the PAS required for immunomodulator (IMID) prescribing should be formally agreed to help train PIPs and assess competency. PIPs and other non-medical prescribers have not previously prescribed IMIDs within SCAN due to the absence of specialist training.

The British Oncology Pharmacist Association competency framework for prescribing SACT specifies that pharmacist independent prescribers need to be competent in patient assessment skills for each specific tumour group[5]. However, it does not detail which patient assessment skills are required for each tumour group. Similarly, the West of Scotland Cancer Network competency framework does not specify PAS required by PIPs prescribing SACT[6].

Previous work has shown which PAS are required for prescribing SACT in the lung and genitourinary (GU) cancer tumour groups[7]. Allison et al. showed some differences between what PAS that would be required for PIPs to prescribe SACT in each respective group. For example, in lung cancer chest examination would be required but not in GU cancer. Furthermore, in lung cancer it would be expected that PIPs could assess the psychological impact of SACT but not for GU cancer. The author concluded that further work must be done to determine what PAS are required for other tumour groups including multiple myeloma.

From the literature review, there is lack of evidence on what the required PAS for PIPs are across all tumour groups except lung and genitourinary cancers. The literature, however, does show that, where pharmacist expertise is utilised, there is an improved benefit to patient satisfaction as well as clinician adherence to treatment guidelines in haematology clinics[8-13]. If PIPs have the required PAS then this would have significant benefit to patient safety and clinical outcomes as PIPs would be able to identify when treatment is working, not working or causing toxicity to the patient. A lack of expertise in PAS within a service, on the other hand, could lead to poorer outcomes for patients or increased safety concerns not helped by the increasing pressure and limited available resources. This study, therefore, aimed to gain consensus on PAS required by PIPs prescribing IMIDs in myeloma across National Health Service Scotland. The objectives were to explore what haematologists think are the PAS required by PIPs

to prescribe IMIDs for myeloma patients, and then to gain consensus across all cancer networks in Scotland on the PAS required by PIPs to prescribe IMIDs for myeloma patients.

## Methods

This was a two-phase study whereby local consensus was gained before National consensus. To gain local consensus, nominal group technique (NGT) was used with a group of haematology specialists within SCAN[14]. A second phase of data collection was carried out using a two-round eDelphi quesionnaire which was circulated to haematology specialist colleagues in the South-East Cancer Network (SCAN), West of Scotland Cancer Network (WoSCAN) and North Cancer Alliance (NCA) to gain National consensus[15-19]. The results were compared to the study by Allison J et al to demonstrate the differences in the required PAS for PIPs prescribing SACT within different tumour groups. [7].

Phase 1 - NGT

NGT was used to explore what NHS haematology specialists think are the PAS required by PIPs to prescribe IMIDs for myeloma patients (Figure 1). Twelve members of the haematology team within SCAN including consultants, specialist registrars, advanced nurse practitioners and pharmacists were invited to participate. An email invite was sent which included a participant information sheet, a consent form and instructions to return this to the investigator, if they were interested to participate, before the nominal group meeting. Participants were also provided with a workbook containing a list of 27 PAS generated from previous work (see appendix)[7], which provided the opportunity for participants to document their thoughts on each PAS prior to the meeting. The 27 PAS were categorised under the following headings: common SACT toxicities; clinical examination skills; complications of cancer/SACT; interpretation of clinical tests; interpretation of clinical reports; and emotional and holistic needs assessment. A reminder email was sent one week after the initial email. Five haematology specialists including two consultants, two advanced nurse practitioners and one pharmacist participated and their expert opinions were used to form consensus on the PAS required to prescribe IMIDs for myeloma patients. The session took place on Microsoft Teams® and was recorded and transcribed to ensure all opinions were captured as qualitative data. Each participant expressed their opinion during the round robin phase, followed by active group discussion. They were then given an opportunity to add additional points or modify what they wanted to express. Any new PAS generated from discussion were added to the initial list of 27 PAS. Each participant was then asked to rank each PAS using a 5-point Likert scale (5 for strongly agree to 1 for strongly disagree) on how strongly they agree or disagree that each PAS is required for PIPs prescribing IMIDs in myeloma. The results were collated using JISC® online survey. At the end of the session the results were summarised and discussed with the group. Consensus on agreement was achieved for each PAS if ≥70% recorded either a 4 or a 5 on the Likert scale mirroring the criteria used in previous published research[7]. Consensus for disagreement was achieved as a negative finding if ≥70% recorded either a 1 or a 2 on the Likert scale. The skills which achieved consensus for disagreement, that is, those that were not deemed relevant to PIP prescribing of IMIDs, were not included in the eDelphi questionnaire for phase 2. Each participant was given the opportunity to express why certain PAS did not achieve consensus. The transcription data was coded on NVivo®. An independent researcher validated 30% of the transcription data. Quotes were taken from the NGT and used as qualitative data to justify findings in the results.

Phase 2 – eDelphi questionnaire

To gain consensus across the SCAN, WoSCAN and NCA, an eDelphi questionnaire (Figure 2) was developed based on the results of the phase 1 NGT. The questionnaire also included PAS which did not gain consensus but it excluded PAS deemed irrelevant by the NGT participants, similar to the study by

Allison J et al[7]. This questionnaire was two rounds. Participants were asked to select within a 7-point Likert scale (1 = strongly disagree; 7 = strongly agree) how strongly they agree or disagree with whether certain PAS are required for PIPs to prescribe IMIDs for myeloma patients. The questionnaire was designed using JISC® online surveys which was then distributed by email. The questionnaire included free-text space within each section for additional comments. An email reminder was sent one week after the initial email. The first questionnaire results were then summarised and analysed using Microsoft Excel®. Consensus on agreement was achieved for each PAS if ≥70% of participants recorded a score of 5-7 on the Likert scale. Similarly, consensus for disagreement was recorded if ≥70% recorded a score of 1-3 on the Likert scale. The PAS which gained consensus were removed from the questionnaire and the remaining PAS were then sent out in a second round JISC online survey via email. The email also contained the median group score and additional comments made by the group from the first-round. The same 7-point Likert scale was used. The results of the second questionnaire were summarised and analysed using Microsoft Excel®.

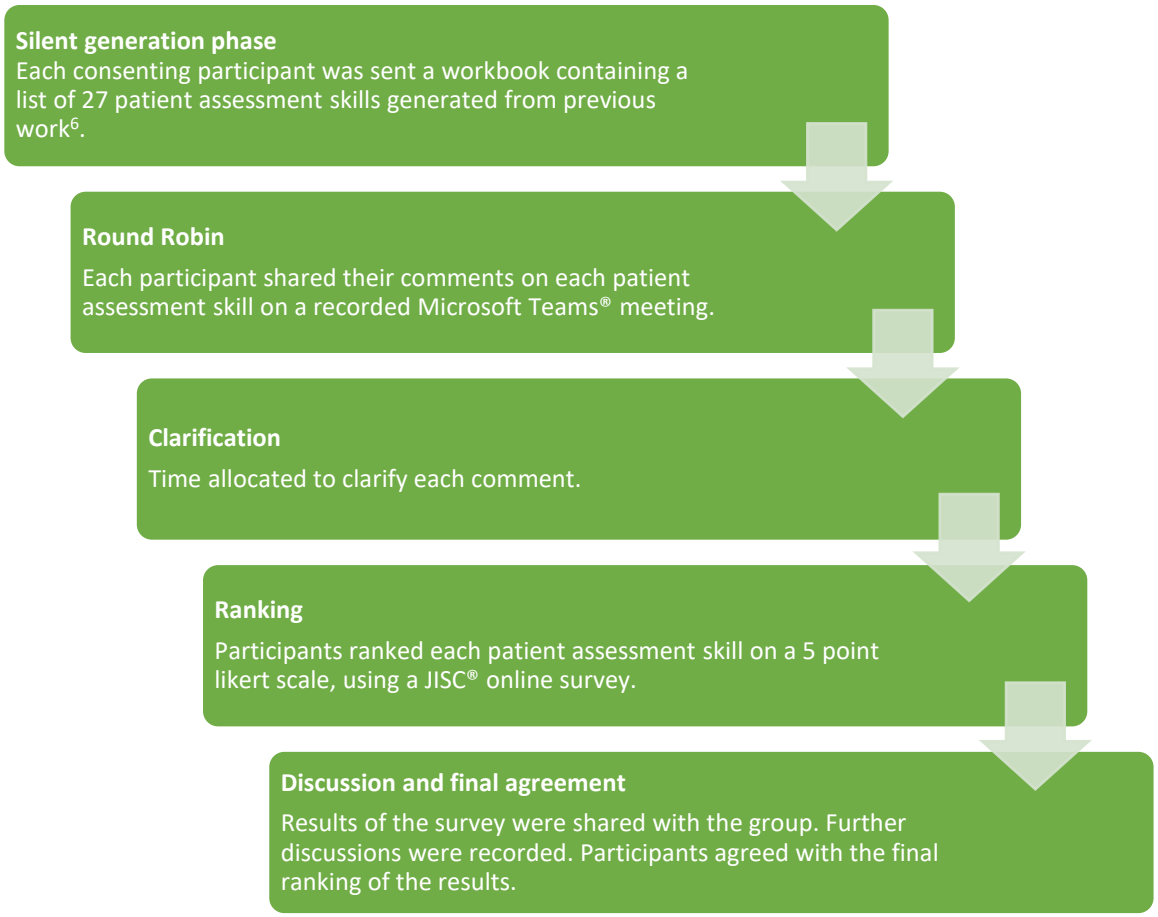


Figure 1. Stages of the nominal group technique process

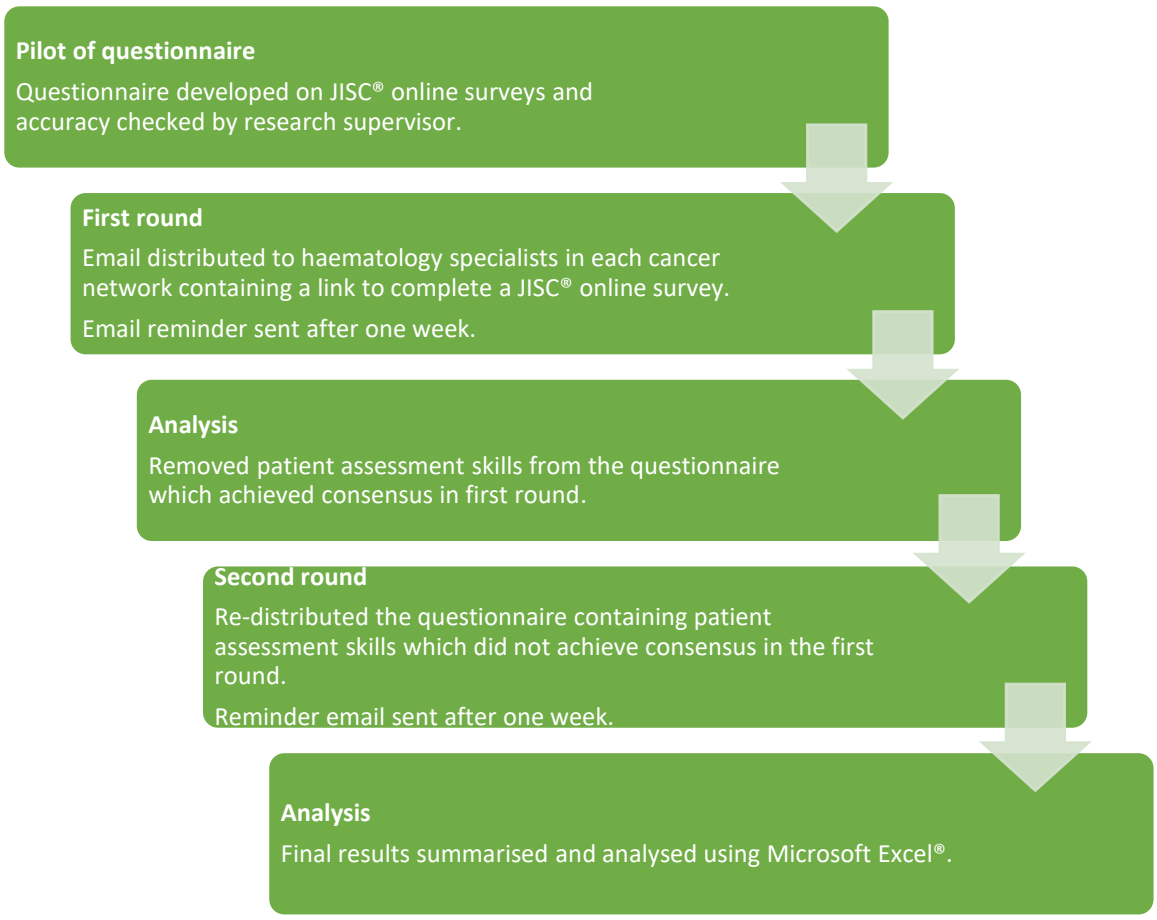


Figure 2. Stages of the eDelphi questionnaire process

Research ethics

As only NHS employees participated in this project, it did not require approval from the NHS Research Ethics Committee. Local approval was granted from NHS Lothian Quality Improvement Team.

## Results

Phase 1 - NGT

The five participants in the NGT group included two haematology consultants, two advanced nurse practitioners and one PIP. During round robin phase of the NGT, the group added four new PAS to the list, giving a total of 31 PAS. The following PAS were added: **PIPs should be able to assess peripheral oedema; PIPs should be able to assess constipation; PIPs should be able to assess for signs of hypoglycaemia/hyperglycaemia; PIPs should be able to recognise signs of venous thromboembolism/pulmonary embolism.**

Twenty-two out of the total 31 (71%) PAS gained consensus after the final ranking of the results (Table 1) and were included in the questionnaire for phase 2.

Table 1. Nominal group technique session results for five participants with 31 patient assessment skills discussed.

| Category | Patient assessment skill statement | Result |
|---|---|---|
| Common SACT toxicities | PIPs should be able to assess performance status | • |
| | PIPs should be able to assess general appearance and well being | • |
| | PIPs should be able to assess nausea and vomiting | • |
| | PIPs should be able to assess diarrhoea | • |
| | PIPs should be able to assess constipation | • |
| Clinical Examination Skills | PIPs should be able to examine the oral mucosa and tongue | • |
| | PIPs should be able to examine the hands | • |
| | PIPs should be able to examine the patient's legs, ankles and feet | • |
| | PIPs should be able to examine the patient's skin (e.g. rash, shingles, chickenpox, cellulitis) | • |
| | PIPs should be able to assess neurotoxicity | • |
| | PIPs should be able to assess pain | • |
| | PIPs should be able to assess vital signs (e.g. BP, HR, temperature, RR) | • |
| | PIPs should be able to perform basic chest examination | Δ |
| | PIPs should be able to perform lymph node palpation | O; – |
| | PIPs should be able to perform abdominal examination | Δ |

| | | |
|---|---|---|
| | PIPs should be able to recognise signs of VTE or PE | • |
| | PIPs should be able to assess for signs of hypoglycaemia/hyperglycaemia | • |
| | PIPs should be able to assess peripheral oedema | • |
| Complications of cancer/SACT | PIPs should be able to identify the signs and symptoms of spinal cord compression | • |
| | PIPs should be able to identify the signs and symptoms of neutropenic sepsis | • |
| Interpretation of clinical tests | PIPs should be able to interpret blood results as per SACT protocol/MPC | • |
| | PIPs should be able to interpret thyroid function test results | Δ |
| | PIPs should be able to interpret mutational status | O; – |
| | PIPs should be able to interpret electrocardiogram results | Δ |
| | PIPs should be able to interpret urinalysis results | Δ |
| Interpretation of clinical reports | PIPs should be able to interpret CT reports | Δ |
| | PIPs should be able to interpret left ventricular ejection fraction reports (e.g. ECHO/MUGA) | Δ |
| | PIPs should be able to interpret X-ray reports | Δ |
| | PIPs should be able to interpret ultrasound reports | Δ |
| Emotional and holistic needs assessment | PIPs should be able to assess the emotional needs and psychological impact of treatment | • |
| | PIPs should be able to carry out a holistic needs assessment | • |

SACT: systemic anti-cancer therapy; PIP: pharmacist independent prescriber; MPC: master prescription chart; CT: computerised tomography; BP: blood pressure; HR: heart rate; RR: respiratory rate; ECHO: echocardiogram; MUGA: multiple gated acquisition; VTE: venous thromboembolism; PE: pulmonary embolism.

•: agree (≥70% of participants voted agree or strongly agree); O: disagree (≥70% of participants voted disagree or strongly disagree); Δ: no consensus; –: considered irrelevant to tumour group.

Nine of the PAS which did not gain consensus were included in the questionnaire for phase 2. Comments on seven of the 31 PAS are provided in Table 2 to justify the results.

Table 2. Comments on seven patient assessment skills which did not gain consensus in the nominal group technique session.

| Comments |
|---|
| **PIPs should be able to perform basic chest examination; PIPs should be able to interpret CT reports; PIPs should be able to interpret X-ray reports; PIPs should be able to interpret ultrasound reports.** Participants advised there may be some relevance for PIPs to have these PAS but they would not always be necessary but we need to be able to refer to medical staff appropriately. *"We need to spend time and we need to think as well and be competent to answer those questions, whether it's related to the SACT or not and make sure that we refer people on to appropriate... looking at sort of interpretation of CT reports, X-ray reports, ultrasound reports other than a chest at well actually, unless it states in the master prescription. If these are not required, it's not necessary."* |
| **PIPs should be able to perform abdominal examination.** Although there was no consensus around this skill, participants highlighted that constipation was an issue therefore this skill may be relevant. *"Constipation is often a big issue as well, with some of them."* |
| **PIPs should be able to interpret thyroid function test results.** There was no consensus on whether this skill should be included although it may be relevant. *"To look for thyroid function tests, but everything outside the range, it becomes a bit more difficult, and perhaps it needs to be. I guess we need for some medical background and some differential. Why that happened and so. You know requesting the tests or reviewing the tests might be important. Make sure that somebody has had thyroid function tests every few months, for example, but interpretation of all that. It may not be absolutely necessary actually, in order for you to prescribe."* |
| **PIPs should be able to interpret urinalysis results.** There was some indication from the NGT that urinalysis might be relevant in the right context however this may not always be relevant. *"If I see a positive urinalysis and we've got sensitivities, then I'm happy to prescribe antibiotics because I have everything I need."* |

No comments were made on the following PAS which did not achieve consensus: **PIPs should be able to interpret electrocardiogram results; PIPs should be able to interpret left ventricular ejection fraction reports (e.g. ECHO/MUGA).**

The group of participants advised that lymph node palpation and interpretation of mutational status were not relevant therefore these were removed from the list of PAS used for phase 2. Comments on these PAS from the group are shown below.

**PIPs should be able to perform lymph node palpation.** *"I wouldn't say it was essential to this group of patients. This is more the lymphoid side."*

**PIPs should be able to interpret mutational status.** *"I think when it comes to mutational status in myeloma, it's something that we discuss at the MDM and things like that right? And you know, I think a decision whether or not to start people on treatment and things like that would have already been made, so it won't probably be relevant to PIPs."*

Phase 2 – eDelphi

Twenty-nine of the 31 PAS included in the NGT were transferred to round one of the eDelphi questionnaire. Round one of the eDelphi questionnaire achieved a 43% response rate with 12 out of the 28 haematology specialists participating. Round two achieved a 50% response rate. Demographics are presented in Table 3 below.

Table 3. Participant demographics of the National eDelphi questionnaire.

| **Cancer Network** | **Number of Participants** | | **Number Invited** |
|---|---|---|---|
| | **Round one (n=12)** | **Round two (n=14)** | **Total = 28** |
| South-East Scotland Cancer Network | 5 | 7 | 14 |
| West of Scotland Cancer Network | 5 | 4 | 9 |
| North Cancer Alliance | 2 | 3 | 5 |
| **Role** | | | |
| Consultant Haematologist | 7 | 8 | 16 |
| Specialist Registrar - Haematology | 1 | 1 | 3 |
| Advanced Nurse Practitioner - Haematology | 1 | 2 | 4 |
| Specialist Pharmacist – Cancer Services | 3 | 3 | 5 |

There were 21/29 PAS which achieved consensus during the first-round questionnaire (Table 4). The eight PAS which did not reach consensus were included in the second-round questionnaire. The PAS statement “PIPs should be able to interpret electrocardiogram results” reached a disagreement consensus. The other seven PAS did not reach consensus for a second time. The results are presented along with the results from the previous work by Allison J et al. for comparison.

Table 4. National questionnaire results for 12 participants in the myeloma group compared to the genitourinary and lung group consensus study by Allison J et al. 2019[7].

| Category | Patient assessment skill statement | Myeloma | GU | Lung |
|---|---|---|---|---|
| Common SACT toxicities | PIPs should be able to assess performance status | • | • | • |
| | PIPs should be able to assess general appearance and well being | • | • | • |
| | PIPs should be able to assess nausea and vomiting | • | • | • |
| | PIPs should be able to assess diarrhoea | • | • | • |
| | PIPs should be able to assess constipation | • | – | – |
| Clinical Examination Skills | PIPs should be able to examine the oral mucosa and tongue | • | – | • |
| | PIPs should be able to examine the hands | • | – | • |
| | PIPs should be able to examine the patient's legs, ankles and feet | • | – | • |
| | PIPs should be able to examine the patient's skin (e.g. rash, shingles, chickenpox, cellulitis) | • | – | • |
| | PIPs should be able to assess neurotoxicity | • | – | • |
| | PIPs should be able to assess pain | • | – | – |
| | PIPs should be able to assess arthralgia | – | • | – |
| | PIPs should be able to assess vital signs (e.g. BP, HR, temperature, RR) | • | • | • |
| | PIPs should be able to perform basic chest examination | Δ | Δ | • |
| | PIPs should be able to perform lymph node palpation | – | O | – |
| | PIPs should be able to perform abdominal examination | Δ | O | Δ |
| | PIPs should be able to recognise signs of VTE or PE | • | – | – |
| | PIPs should be able to assess for signs of hypoglycaemia/hyperglycaemia | • | – | – |
| | PIPs should be able to assess peripheral oedema | • | – | – |
| | PIPs should be able to identify the signs and symptoms of spinal cord compression | • | • | • |

| | | | | |
|---|---|---|---|---|
| Complications of cancer/SACT | PIPs should be able to identify the signs and symptoms of neutropenic sepsis | • | • | • |
| Interpretation of clinical tests | PIPs should be able to interpret blood results as per SACT protocol/MPC | • | – | – |
| | PIPs should be able to interpret thyroid function test results | • | • | – |
| | PIPs should be able to interpret mutational status | – | – | • |
| | PIPs should be able to interpret electrocardiogram results | O | Δ | • |
| | PIPs should be able to interpret urinalysis results | Δ | • | – |
| Interpretation of clinical reports | PIPs should be able to interpret CT reports | Δ | – | Δ |
| | PIPs should be able to interpret left ventricular ejection fraction reports (e.g. ECHO/MUGA) | • | Δ | • |
| | PIPs should be able to interpret X-ray reports | Δ | • | Δ |
| | PIPs should be able to interpret ultrasound reports | Δ | Δ | Δ |
| Emotional and holistic needs assessment | PIPs should be able to assess the emotional needs and psychological impact of treatment | • | • | • |
| | PIPs should be able to carry out a holistic needs assessment | Δ | Δ | • |

SACT: systemic anti-cancer therapy; PIP: pharmacist independent prescriber; MPC: master prescription chart; CT: computerised tomography; BP: blood pressure; HR: heart rate; RR: respiratory rate; ECHO: echocardiogram; MUGA: multiple gated acquisition; VTE: venous thromboembolism; PE: pulmonary embolism; GU: genitourinary cancer

•: agree (≥70% of participants voted slightly agree, agree or strongly agree); O: disagree (≥70% of participants voted slightly disagree, disagree or strongly disagree); Δ: no consensus; –: considered irrelevant to tumour group.

Three PAS achieved different outcomes between the NGT and eDelphi consensus methods (Table 5).

Table 5. Differences between the nominal group technique session and eDelphi questionnaire results.

| Category | Patient assessment skill statement | NGT result | eDelphi result |
|---|---|---|---|
| Interpretation of clinical tests | PIPs should be able to interpret thyroid function test results | Δ | • |
| | PIPs should be able to interpret electrocardiogram results | Δ | O |
| Interpretation of clinical reports | PIPs should be able to interpret left ventricular ejection fraction reports (e.g. ECHO/MUGA) | Δ | • |
| Emotional and holistic needs assessment | PIPs should be able to carry out a holistic needs assessment | • | Δ |

ECHO: echocardiogram; MUGA: multiple gated acquisition

•: agree (≥70% of participants voted slightly agree, agree or strongly agree); Δ: no consensus; O: disagree (≥70% of participants voted slightly disagree, disagree or strongly disagree)

Seven out of the 29 suggested PAS did not achieve consensus after the eDelphi (see table 6 for comments). It was evident from the comments there is no expectation that a PIP would be solely responsible for using these PAS and that if any abnormality was found then this should be referred to the consultant haematologist. There was only one PAS which gained disagreement consensus: "PIPs should be able to interpret electrocardiogram (ECG) results". It was the general consensus from the participants that ECGs should not be the responsibility of PIPs. Some of the comments are provided below which represent all themes:

- *"ECG interpretation should be done by others but pharmacist should recognise when ECG machine report highlights something abnormal to bring it to attention of doctor" – Consultant Haematologist 1*
- *"Would expect to get input to abnormal ECG unless specific abnormality e.g. QTc was being looked for" – Consultant Haematologist 2*
- *"Interpretation of ECG requires a lot of knowledge - misinterpretation can lead to disaster" – Consultant Haematologist*
- *"With the exception of printed figures e.g. QT interval and of rate/rhythm e.g. atrial fibrillation" – Consultant haematologist 5*
- *"Not routinely indicated at follow up visits" – Consultant haematologist 6*

Table 6. Patient assessment skills which did not gain consensus in the eDelphi questionnaire.

| Comments |
|---|
| **PIPs should be able to perform basic chest examination**<br>*"PIPs should be able to ask questions about the presence of the above toxicities. However, I would expect them to be able to discuss e.g. rash, neuropathy examination, chest findings." – Consultant Haematologist 3* |
| **PIPs should be able to perform abdominal examination**<br>*"Chest or abdominal examination may not be critical skills.*<br>*If any concerns raised by the patient or by vital signs further examination may be performed by a medic or ANP." – Consultant Haematologist 2* |
| **PIPs should be able to interpret urinalysis results**<br>*"PIPs need to know why these clinical tests are being carried out and again be aware of results which might indicate that the patient is not responding or may have a side effect of the drug in order to be able to escalate to medical staff." – Pharmacist 1* |
| **PIPs should be able to interpret CT reports**<br>**PIPs should be able to interpret X-ray reports**<br>**PIPs should be able to interpret ultrasound reports**<br>*"Again - pharmacist would merely need to understand when a report is highlighting something significant so it can be brought to attention of medic/ANP" – Consultant Haematologist 1*<br><br>*"PIP a should have a level of knowledge that allows them to interpret scan and other investigation results but should have support of MDT to be able to discuss results and implications for the patient." – Advanced Nurse Practitioner 1*<br><br>*"Some reports are easier to interpret than others but they should be able to see if there is an abnormal report and take advice." – Consultant Haematologist 3* |
| **PIPs should be able to carry out a holistic needs assessment**<br>*"This is what nurses are trained for." – Consultant Haematologist 1*<br><br>*"PIP needs an awareness of the psychological impact of treatment in order to be able to discuss within the MDT. Don't agree that they necessarily need to be able to carry out a holistic needs assessment." - Pharmacist 1*<br><br>*"It is important to be able to care for patient as a whole rather than just the role of prescriber. Becomes very disjointed if patient has to look elsewhere for psychological support. Also psychological effects can impact of physical condition and toxicities experienced." - Advanced Nurse Practitioner 1* |

ECG: electrocardiogram; CT: computerised tomography; MDT: multi-disciplinary team; QTc: corrected QT interval; ANP: advanced nurse practitioner

## Discussion

*Key Findings*

In this study, participants were asked for their opinion on which PAS were required for PIPs prescribing of IMIDs in myeloma. The PAS which were identified as specific to the myeloma group during NGT discussion were: assessment of constipation; assess for signs of venous thromboembolism/pulmonary embolism; assess for signs of hypoglycaemia/hyperglycaemia; assess for peripheral oedema. These PAS were not generated in previous work for the other tumour groups (GU and lung).

There are currently no PIPs in Scotland prescribing IMIDs in myeloma, therefore the PAS which achieved consensus (Table 4) could form a competency framework for PIPs prescribing IMIDs in myeloma. The differences between data collected between the NGT meeting and eDelphi questionnaire are highlighted in Table 5. A reason for the differences might be due to alternative practice across the cancer networks. For example, advanced nurse practitioners (ANPs) do not prescribe IMIDs in all cancer networks. SCAN has ANPs who prescribe IMIDs but only at some local centres therefore practice will vary between regions. This practice has been established on an individual basis at different localities to cope with service demand. These local arrangements have been adopted after agreement between the individual ANPs and consultant haematologists on the expected competencies to prescribe IMIDs for myeloma patients. Differences in practice between cancer networks would need to be considered if developing a competency framework.

The comments on the PAS which did not achieve consensus highlighted pertinent themes. PIPs are not expected to be able to perform all PAS. However, they should be able to highlight abnormalities and refer appropriately to an ANP or consultant. In these cases, the appropriate person could review the reports and make the decision to continue treatment, hold or discontinue treatment for a patient. Disease progression may be evident from these reports therefore the consultant would need to speak to the patient about further options. This would indicate that a multi-disciplinary team approach is important and that PIPs should not be expected to work in isolation There were comments on interpretation of ECGs, highlighting that PIPs could interpret a QTc interval which is useful for making decisions about drug interactions with concomitant medicines and IMIDs or supportive treatments such as anti-emetics. Across both phases of data collection, the ability to assess for signs of VTE/PE gained consensus for agreement. This is important as this adverse effect is common in patients taking IMIDs[20]. One of the supportive treatments in SCAN for patients taking IMIDs is apixaban for the prevention of VTE/PE during the first 4-6 months of IMID treatment and this indication is off-label[21]. Pharmacists have lots of experience in clinical verification and counseling of patients taking apixaban, providing education on signs of bleeding and when to report this to their doctor. Therefore, pharmacists are already demonstrating some competence in recognizing and managing the supportive treatments for IMIDs.

The comparison between studies in Table 4 highlights the similarities and differences between PAS requirements for PIPs in different settings. For example, assessment of constipation, pain, VTE/PE, hypo/hyperglycaemia and peripheral oedema were additional PAS agreed for IMIDs in myeloma,compared to the lung and GU group in a previous study. Pharmacists have already built a good and reliable reputation working in oral SACT outpatient clinics according to surveys of patient experiences[8, 9, 11-13, 22, 23]. However, pharmacists are subject to scrutiny over their clinical assessment skills as they were traditionally non-patient facing roles. It was previously felt that pharmacists were reluctant to examine patients[24-27]. This study, in combination with government objectives, demonstrates

that the profession is changing in addition to the perception of the role within the multidisciplinary team. Since the developments of Allison J et al. there is now service level agreements and a competency framework in place for SACT prescribing by non-medical prescribers in SCAN for prostate and breast cancer[28-30]. This is in addition to the prescribing competency frameworks outlined by the Royal Pharmaceutical Society (RPS), British Oncology Pharmacy Association (BOPA) and WoSCAN which do not specify which PAS are required[5, 6, 31]. This research could inform development of a competency framework for PIPs prescribing IMIDs in myeloma.

*Strengths and limitations*

Where no published research is available on a given subject, a group of experts may provide their opinions on it to achieve consensus. NGT and eDelphi are consensus methods which allow for a small or large group, respectively, to achieve consensus[14]. Both methods were used to increase the validity of the results as there are a relatively small number of clinicians working in this area compared to other specialties. As the NGT was conducted in this study through a Microsoft Teams® meeting, it allowed clinicians to engage in active discussion before ranking their results. However, the larger group participating in the eDelphi questionnaire only allowed participants to anonymously document their comments on the PAS without hearing the rationale for other partcipants' decision making. The anonymity allows each participant to freely express their opinion without fear of disagreement. There are no fixed criteria on what percentage of agreement is required to achieve consensus as studies in the literature vary between ≥70-80%[15-19]. In this study 70% was chosen due to the relatively small number of clinicians working in this area in Scotland. If a larger multi-national study was conducted then the percentage could be set higher to 80% to increase precision. Five out of 13 (38%) participants invited to the NGT meeting attended and the literature documents a range of participants between 2-15[14]. This number of participants is lower compared to previous studies. This was due to several factors including participants clinical commitments, competing time pressures, sickness and annual leave. The eDelphi invited 29 clinicians to participate in the questionnaire and 41% of those responded which is similar to the percentage of respondents in the lung group in the previous study[7]. Better engagement in the eDelphi compared to NGT may be due to participants having more flexibility around the timing of their engagement and the anonymity of their opinions. The sample size for a Delphi questionnaire is determined by the availability of participants and is not fixed[15]. There was a low number of pharmacists who participated in the study due to the lack of pharmacists who work specifically with myeloma patients. From review of the literature, pharmacists are more involved in this area of practice in England compared to Scotland[8]. From discussion with a colleague working in England, there are already pharmacists prescribing IMIDs in England although no formal research was carried out to gain consensus on which PAS were required[32]. Findings of this study will be shared with colleagues in England to determine where this study fits in relation to practice elsewhere.

*Implications for future practice*

The findings from this study could be used to implement the introduction of a PIP to prescribe IMIDs in a clinic for myeloma patients under consultant supervision in Scotland. A service development proposal would be required to demonstrate the impact of implementing this in within each cancer network. Evaluation of the current service will be required for reference. The service development proposal will also highlight the barriers to implementing this new service and how these barriers will be overcome. Potential barriers include the completion electronic prescription authorisation forms (ePAFs) which are a

legal requirement for treatment with IMIDs due to the risk of fetal malformations in women of childbearing potential. A solution to this issue would be to work with the consultant to ensure ePAFs are generated in advance of appointments and the PIP can verify these if IMIDs are dispensed and reject them if a patient needs to stop treatment.

The Scottish Government strategy (Achieving Excellence in Pharmaceutical care – 2017) outlined that undergraduate programmes would now ensure that all pharmacy students would gain competence in clinical skills required for prescribing activities. This includes the core skill of vital sign measurements[33]. This was previously missing from undergraduate programmes. Furthermore, the new foundation pharmacy framework introduced by the Royal Pharmaceutical Society in 2019 outlines that pharmacists will now be required to demonstrate competence in conducting patient clinical examinations and assessments[34, 35]. NHS education for Scotland mandate that any pharmacist undertaking independent prescriber training must attend a clinical skills course at The University of Dundee[36]. This provides experience in measuring of vital signs, basic chest examination and consultation skills but they are not tailored towards prescribing IMIDs. Therefore, further training of PIPs must be provided by haematology consultants and they must assess competence after this training.

The findings in this study can be used to help future research into PIPs prescribing SACT for other haematological malignancies such as lymphoma. Any competency framework that is developed using findings from this study should be reviewed regularly when treatment options change or to identify areas for improvement. The only other study which used consensus methods to develop a competency framework for prescribing focused on heart failure[37]. This study linked its competency framework to the domains specified with the advanced pharmacist framework outlined by the RPS. Any development of a competency framework for prescribing IMIDs in myeloma should correlate to this framework to ensure it is relevant to the rest of the UK. In addition to this, experienced PIPs are now expected to undertake a designated prescribing practitioner (DPP) role to deliver training to trainee independent prescribers[38]. A DPP who prescribes IMIDs for myeloma patients, would take responsibility for assessing the competence of PIPs who are learning to prescribe in this area. The DPP competency framework highlights that DPPs need to negotiate sufficient time for supporting the trainee throughout their period of learning in practice (PLP). Competency of each pharmacist can be assessed using a variety of direct or indirect observations of supervised learning events using the core advanced pharmacist curriculum[35]. A competency framework based on the PAS identified in this research would aid the training and assessment process for both DPPs and trainee PIPs.

**Conclusion**

This research outlines 21 PAS required for PIPs to prescribe IMIDs for myeloma patients according to haematology specialists in Scotland. There was no consensus on 8 PAS but the discussion showed that the PIP and the consultant would have a shared responsibility of these PAS. This work should inform the development of a competency framework to allow training and competency assessment of PIPs in Scotland. Furthermore, the PAS could be transferrable for PIPs who are required to prescribe SACT for other haematological malignancies. These findings should be shared with other PIPs who prescribe IMIDs in England which will enable them to evaluate their own practice.

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**Appendix – NGT workbook**

| Category | Patient assessment skill | Comments |
|---|---|---|
| Common SACT toxicities | Assessment of performance status | |
| | Assessment of general appearance and well being | |
| | Assessment of nausea and vomiting | |
| | Assessment of diarrhoea | |
| Clinical examination skills | Examination of oral mucosa and tongue | |
| | Examination of hands | |
| | Examination of legs, ankles and feet | |
| | Examination of skin (e.g. rash, PPE) | |
| | Assessment of neurotoxicity | |
| | Assessment of arthralgia | |
| | Measuring and interpreting vital signs (BP, HR, temperature, RR) | |
| | Basic chest examination | |
| | Lymph node palpation | |
| | Abdominal examination | |
| Complications of cancer/SACT | Identifying signs/symptoms of spinal cord compression | |
| | Identifying signs/symptoms of neutropenic sepsis | |
| Interpretation of clinical tests | Interpretation of thyroid function tests results | |
| | Interpretation of pulmonary function tests results | |
| | Interpretation of tumour markers | |
| | Interpretation of electrocardiogram results | |
| | Interpretation of left ventricular ejection fraction reports, e.g. ECHO/MUGA | |
| Interpretation of clinical reports | Interpretation of urinalysis results | |
| | Interpretation of CT reports | |
| | Interpretation of X-ray reports | |
| | Interpretation of ultrasound reports | |
| Emotional and holistic needs assessment | Assessment of emotional needs and psychological impact of treatment | |
| | Holistic needs assessment | |

Workbook for nominal group technique (NGT) meeting: to gain consensus on the patient assessment skills required for pharmacist independent prescribers to prescribe immunomodulators in myeloma. Generated from work by Allison J et al[7].