

EAHP Summit 2014

Delphi Round 1

Full Report

Professor Neal Maskrey
January 2014

FULL REPORT OF DELPHI ROUND 1

Background

EAHP is developing European Statements on Hospital Pharmacy to form a shared expectancy between hospital pharmacists, patients and healthcare professionals on the practice of hospital pharmacy across Europe.

The statements, which will be voted on at the [European Summit on Hospital Pharmacy](#) (14-15 May 2014) will form the basis of EAHP's work in developing hospital pharmacy standards across Europe, provide an ongoing focus for its educational activity, and a bedrock of pan-European practice benchmarking. The statements will constitute the expectancy of hospital pharmacy service delivery in European countries.

The work develops from the 2008 *Global Statements of Hospital Pharmacy Practice* developed by the International Pharmaceutical Federation (FIP) and known as '[the Basel Statements](#)'. The proposed European statements, as put forward at the commencement of Delphi Round 1, were developed via a review of the Basel Statements by a working group of hospital pharmacists from across Europe, led by EAHP Director of Professional Development Aida Batista.

To ensure the statements reflect the full diversity of national health systems, and the shared aspirations of hospital pharmacists, patients and healthcare professionals, EAHP is conducting a rigorous Delphi consensus finding consultation. What follows is an Executive Summary of the first round of Delphi consultation conducted between the 15th November 2013 and the 6th December 2013.

Nominated delegates from EAHP's 34 national member associations, alongside 34 European patient and professional groups who had registered to be part of the European Summit on Hospital Pharmacy (14-15 May 2014), were invited to take part in the consultation process.

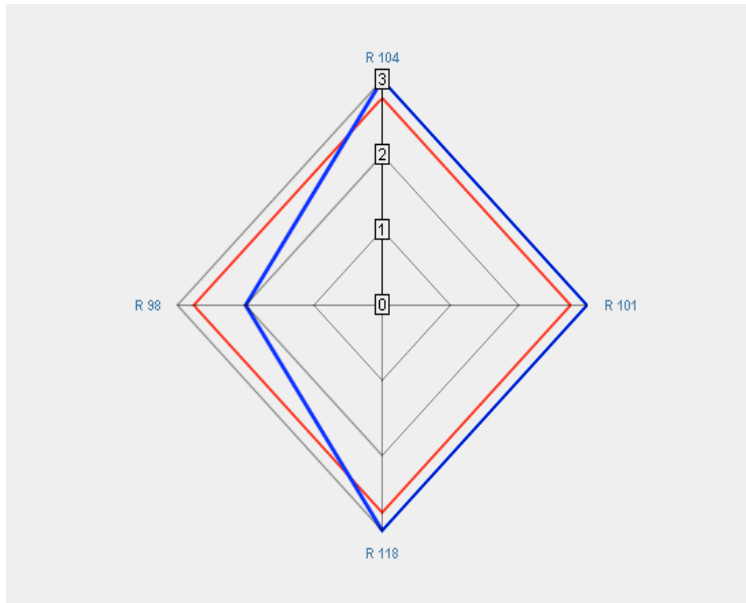
Participants voted and commented on all 48 statements. In Delphi Round 1, 28 statements achieved strong agreement, with the remaining 20 achieving agreement. Following the close of the deadline for Delphi Round 1, the independent moderation and facilitation team led by Professor Neal Maskrey reviewed the debates and the points raised during the consultation and prepared recommendations for statement amendment:

- In most cases, clarification of wording, small typographical or grammatical changes have been made. In a minority of statements new portions and elements to a statement have been recommended as would be expected in a Delphi process.
- No new statements were proposed.
- One statement (previous 3.9) has been moved to the section on clinical services (new 4.4), with corresponding change to all running orders.

Aspect: Introductory Statements and Governance

1.1 The overarching goal of hospital pharmacists is to optimise patient outcomes through the judicious, safe, efficacious, appropriate, and cost effective use of medicines. (Statement 1).

Patient groups

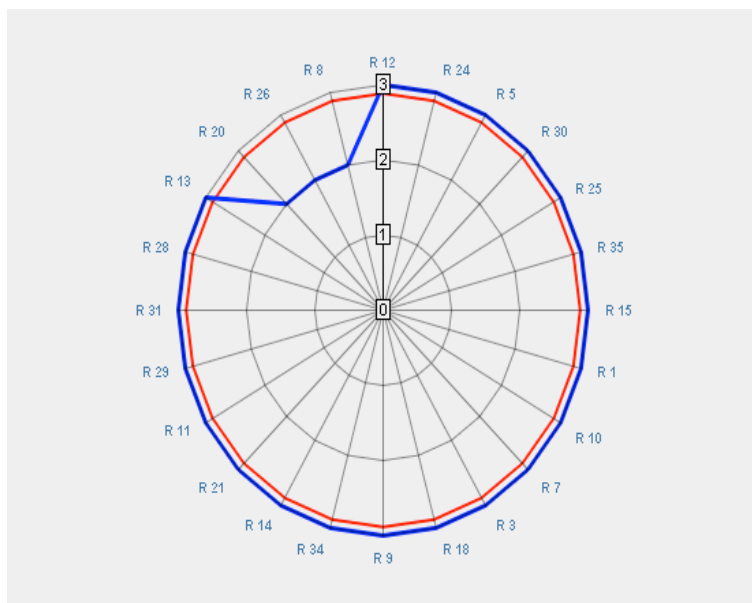


Average score: 2.75

Four responses; the one response not strongly agreeing commented "Overall, the role of HPs requires more public awareness and scrutiny as the focus tends to be on community pharmacists who have more direct contact with patients."

Conclusion: rewording this statement is unlikely to improve consensus.

EAHP Members



Average score: 2.88

The first key comment was:-

“Strongly agree but hospital pharmacists should have opportunity for pharmaceutical care by direct contact with the patients.”

Then clarification about the use of the word “judicious” was required:-

“In contrast to the other words (safe, efficacious...) I have difficulties to find a translation (one single word) to German for ‘judicious’. I don’t understand, what it means in correlation with the “use of medicines”... Could you give me an example?”

The moderator responded *“Within his original definition, Sackett stresses how important it is for practitioners to use their judgment to apply evidence to the individual patient.”*

Then the point was made that “The cost effective use of medicines should be implemented via multidisciplinary collaboration with other health care professionals” and a revised statement constructed:-

The overarching goal of hospital pharmacists is to optimise patient outcomes through working in multidisciplinary teams and carrying out the judicious, safe, efficacious, appropriate, and cost effective use of medicines.

Finally a comment returned to the issue of direct patient care, this time including prescribing rights:-

“provided it is for the benefit of the patient and with their informed agreement, it is expected that pharmacists will achieve this through responsibility for delivery of the therapeutic plan including prescribing.”

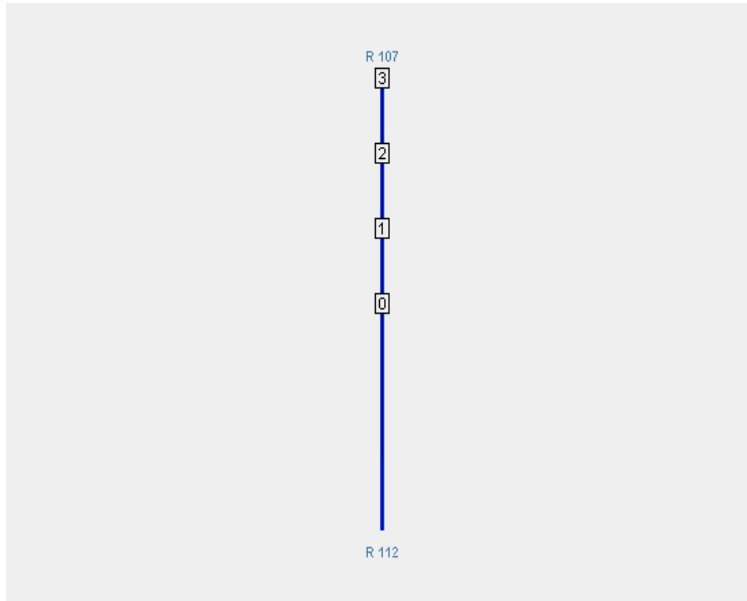
Conclusion:

So much of modern health care involves multidisciplinary teams that a revised statement which reflects that truism adds strength to this statement, despite it already achieving good consensus. The issues of direct patient care and prescribing can best be reflected in later, more detailed statements.

Action: Revise this statement for Delphi 2 to read:-

The overarching goal of the hospital pharmacy service is to optimise patient outcomes through working within multidisciplinary teams in order to carry out the judicious, safe, efficacious, appropriate, and cost effective use of medicines.

Partner health organisations



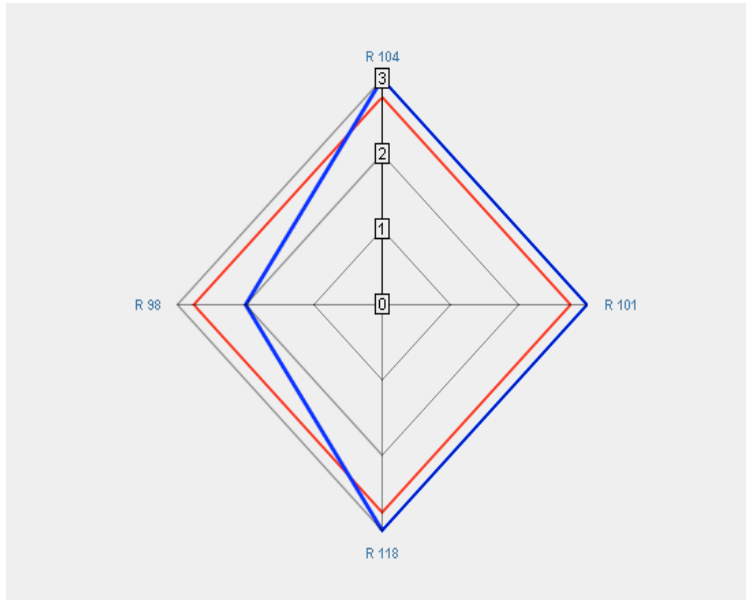
Average score: 3.0

Action: revised proposed statement for Delphi 2 is:-

The overarching goal of the hospital pharmacy service is to optimise patient outcomes through working within multidisciplinary teams in order to carry out the judicious, safe, efficacious, appropriate, and cost effective use of medicines.

1.2 At a European level, 'Good Hospital Pharmacy Practice' guidelines based on evidence should be developed. These guidelines should assist national efforts to define recognised standards across the levels, coverage, and scope of hospital pharmacy services and should include corresponding human resource and training requirements. (Statement 2).

Patient groups



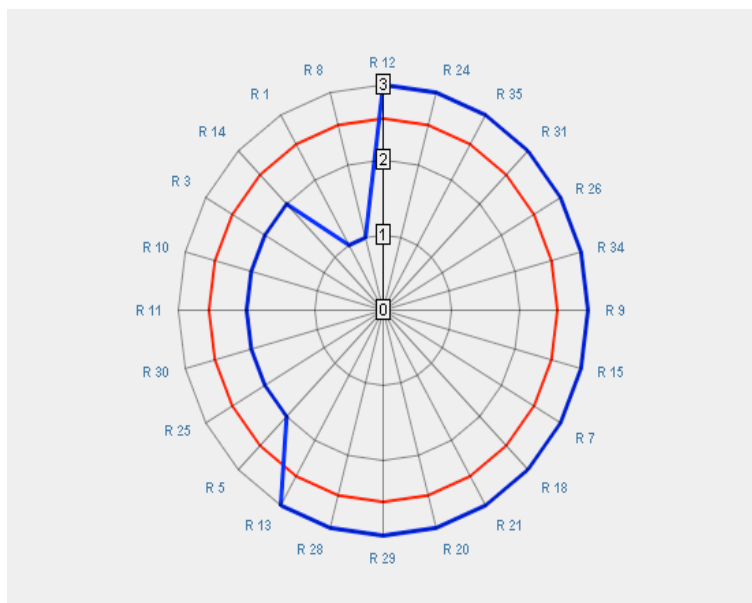
Average score: 2.75

Key comment:-

Guidelines are important and should include patients' perspectives and needs

Conclusion: This is an important point and its inclusion in the statement is justified. Revised statement to be constructed after consideration of other comments on this statement.

EAHP Members



Average score: 2.54

Discussions commenced with the readily accepted point that such guidelines should be “based on best-available evidence” rather than just “evidence”.

Then a debate ensued on the available evidence for staffing levels and the risks that such guidelines may define the minimum rather than the optimum staffing:-

“I think that these standards must define, how much staff is needed for pharmaceutical care and other activities in the hospital pharmacy (eg conducting of pharmaceutical care requires one pharmacist per 2,000 cases of treatment). We should also sets time frames for implementation of these standards.”

“An excellent model - HPMM/ High Performance Medicines Management/ is developed in Sweden and currently used at Swedish hospitals. The model covers three domains and 110 criteria - strategic level, drug handling and patients drug use within the healthcare system. This could pose as a model for Europe to create a common standard for hospital pharmacy since the model will raise the bar and the standard for the HP function.”

“Isn't it important to include the minimum human resource and training requirements in order to meet the guidelines?”

“If you define a minimum human resource, a hospital director possibly would give you this minimum (but never more) - the same if you define a range. Then, on which reference parameter would you calculate the staff needed? number of beds, patients, clinical visits, medication packages, medical orders - including/excluding ambulatory settings? None of these would reflect the complexity of a patient and a hospital. For example a university children's hospital would need much more staff then a "normal" regional hospital. If you integrate a minimum of human resource, high specialized institution would be losers. Furthermore, the education of hospital pharmacists and especially the education of pharmaceutical assistants vary in different countries - it does not exist a useful standardization. In summary, you would always compare "apples with pears" - we say in Switzerland.”

“I agree and think that human resources would be very difficult to define... However if the guidelines are enough precise they can be a support to pharmacists in every country to negotiate the number of pharmacists needed.”

The statement should end with "services": "At a European level, 'Good Hospital Pharmacy Practice' guidelines based on [the best available] evidence should be developed. These guidelines should assist national efforts to define recognised standards across the levels, coverage, and scope of hospital pharmacy services."

provided it is about raising the common standard to those of the highest quality not a median of the norm. it would be

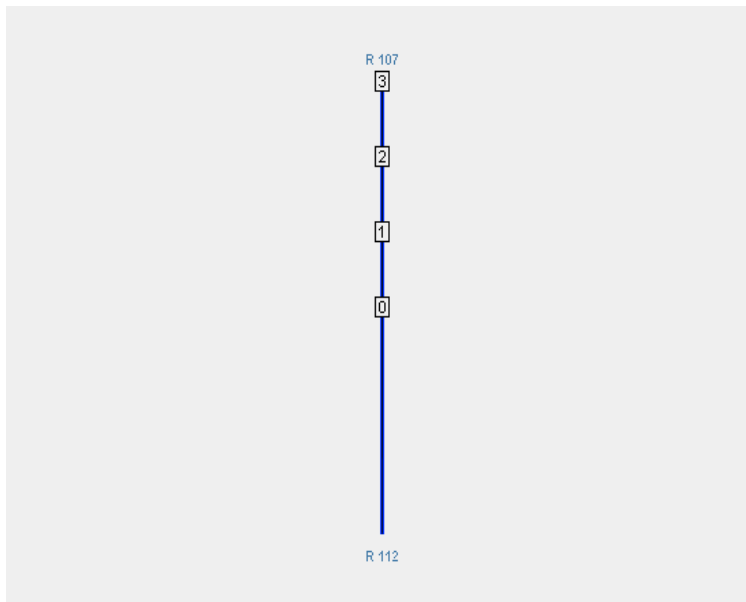
“totally unacceptable to have a lowering to those of the minimum to achieve compliance”

Finally, coverage and scope were considered tautology and a final revised version was suggested.

At a European level, ‘Good Hospital Pharmacy Practice’ guidelines based on the best available evidence should be developed. These guidelines should assist national efforts to define recognised standards across the scope and levels of hospital pharmacy services and should include corresponding human resource and training requirements.

Conclusion: revise statement 2 in accordance with the Dephi 1 suggestions as above. This should achieve even better consensus.

Partner health organisations



Average score: 3.0

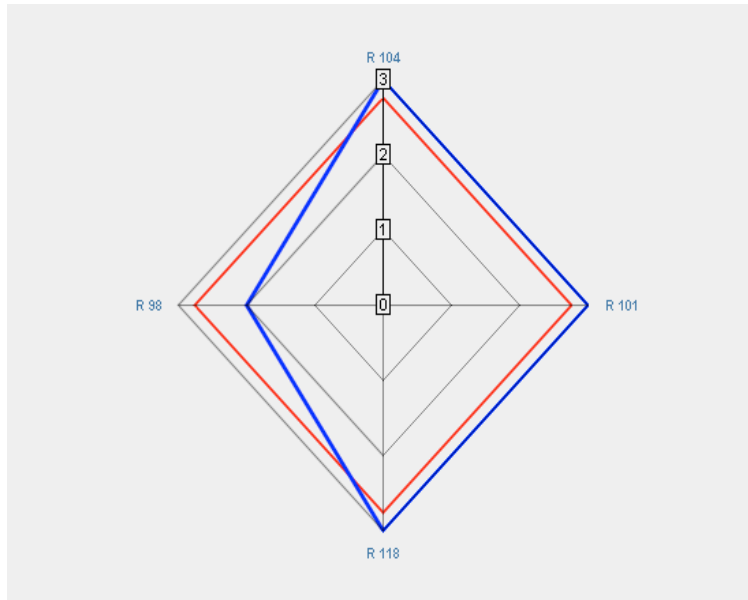
No significant responses were received from partner health organisations.

Action: Revise this statement for the Delphi 2 process to read:-

At a European level, ‘Good Hospital Pharmacy Practice’ guidelines based on the best available evidence should be developed. These guidelines should assist national efforts to define recognised standards across the scope and levels of hospital pharmacy services and should include corresponding human resource and training requirements.

1.3 Health authorities should ensure that each hospital pharmacy should be supervised by a pharmacist who has completed adequate training in hospital pharmacy. All Hospitals must have access to Hospital Pharmacy Services, including those without a Pharmacy in the Hospital. (Statement 3).

Patient groups



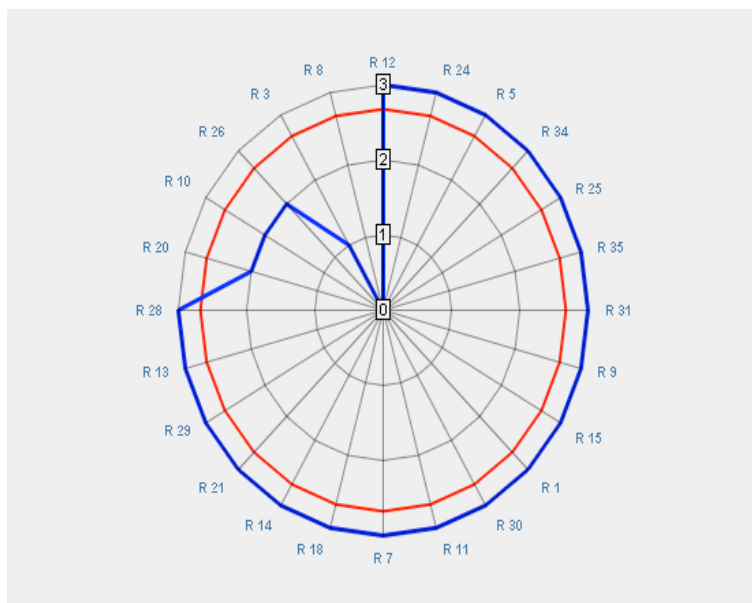
Average score: 2.75

The only comment reflecting less than full agreement was *"This would appear to be an ideal scenario."*

This may reflect the availability of resources in one or more countries, but this should not be a deterrent to recommending the necessary medicines expertise be available everywhere.

Conclusion: it is difficult to make an amendment to the statement which reflects the resource reality without undermining the strength of the statement itself.

EAHP Members



Average score: 2.67

This statement generated significant discussion within the Delphi process.

There was little dissent with the second part of this statement. Much centered on the phrase "adequate training".

"I believe that, in addition to appropriate training, appropriate professional experience is also necessary. For someone who has just finished training and does not have a lot of experience working in a hospital pharmacy, it will be difficult to supervise."

After encouragement from the moderator, the commentator suggested an amendment:-

Health authorities should ensure that each hospital pharmacy should be supervised by a pharmacist who has completed adequate training and work experiences in hospital pharmacy

Other comments recognised that simple experience was insufficient and there was a need for formal training and explicit demonstration of competence:-

"Although I agree with this statement, I feel that small countries might require more time and training programs to get people trained to get the expertise required. "Training" might be explained as both hospital pharmacy specialisation or certificate, not the years of practice or experience.

"Due to the important responsibility of hp activities, the head of a hospital pharmacy should be experienced and have additional, specialised training.

I am not confident with the term adequate training in hospital pharmacy. It should be included specialisation in hospital pharmacy (This is very important for me).

A further revision was suggested:-

Health authorities should ensure that each hospital pharmacy should be supervised by a pharmacist with a sufficient working experience in the hospital settings or with a specialisation in hospital pharmacy. All Hospitals must have access to Hospital Pharmacy Services, including those without a Pharmacy in the Hospital.

Other comments expressed concerns about practical difficulties in certain countries:-

"I wanted to say that the final assessment shouldn't be only the specialisation in HP. In our country we have only about 50 hospital pharmacies, one in a city, and the specialisation in HP would limit our flexibility to get a job. Now we have a specialisation in general pharmacy, which is needed as well in the HP and community pharmacy and then the certificate or the second specialisation (in HP) would be more appropriate."

"In my country there is no available hospital pharmacy training program. Is there some definition what is senior professional? Are the requirements same for all hospitals (no matter about the size, specialty or services)?"

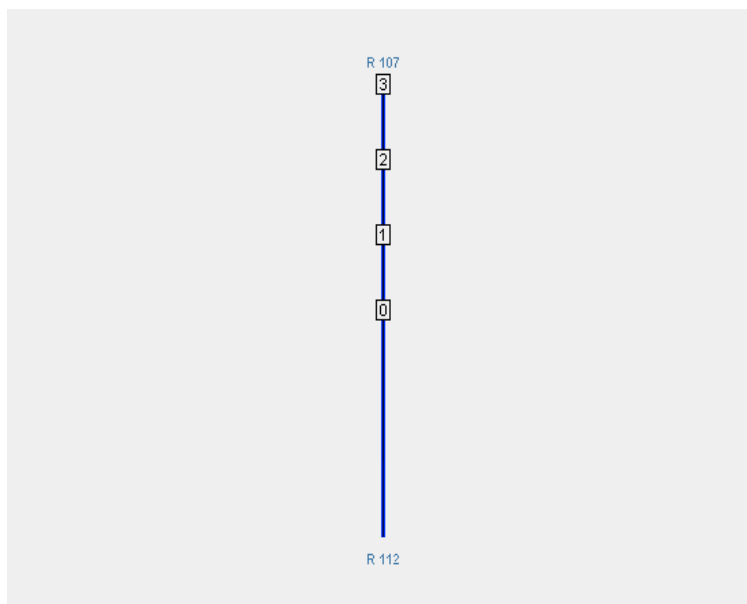
Finally, a wording change was suggested:-

"Health authorities should ensure that each hospital pharmacy is supervised ..."

Conclusion: Taking all comments into account, the statement should be revised for the Delphi2 process:-

Health authorities should ensure that each hospital pharmacy is supervised by a pharmacist with sufficient working experience in the hospital settings, and preferably with explicit, specialist training and demonstration of competence in hospital pharmacy. All hospitals must have access to hospital pharmacy services, including those without a pharmacy in the hospital.

Partner health organisations



Average score: 3.0

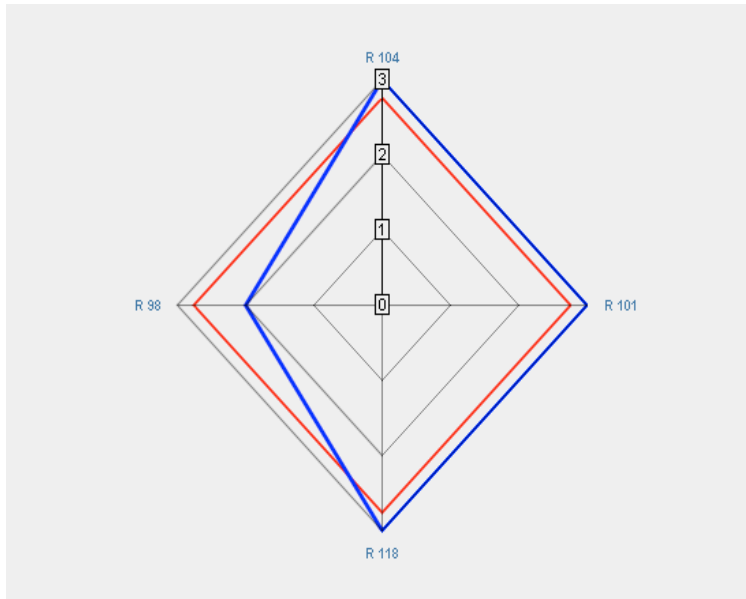
With limited responses and full agreement from partner organisations, no further amendments for Delphi 2 are required to this statement.

Action: Revise this statement for the Delphi 2 process to read:-

Health authorities should ensure that each hospital pharmacy is supervised by a pharmacist with sufficient working experience in hospital settings, and preferably with explicit, specialist training and demonstration of competence in hospital pharmacy. All hospitals must have access to hospital pharmacy services, including those without a pharmacy in the hospital.

1.4 Health authorities and hospital administrators should bring together stakeholders to collaboratively develop and utilise evidence-based hospital pharmacy human resource plans. These should be aligned to engage hospital pharmacists in all steps of medicine use processes and to meet health needs and priorities across public and private sectors that optimise patient outcomes. (Statement 4).

Patient groups



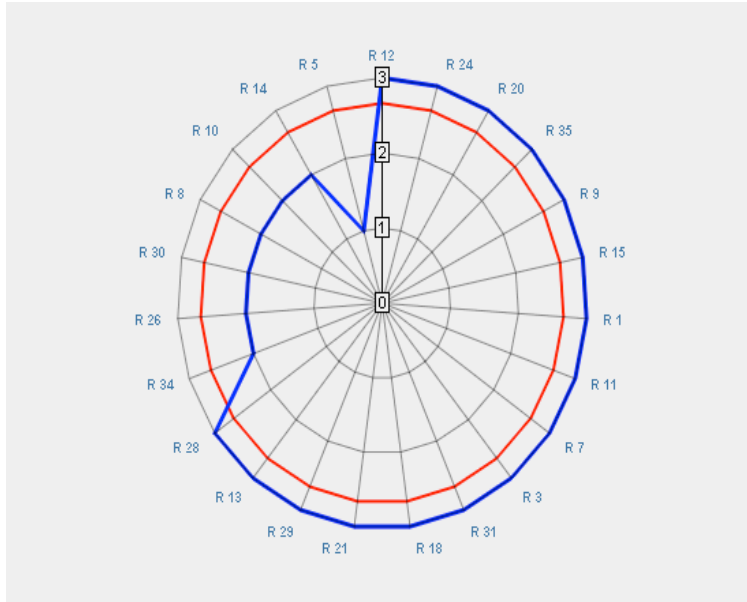
Average score: 2.75

The only comment associated with less than complete agreement was actually entirely supportive:-

"HPs role in medicine use processes appears to be particularly valuable."

Conclusion: No amendment to this statement required on the basis of comments from patient groups.

EAHP Members



Average score: 2.65

Initial comments focused on staff shortages:-

"I believe that the statement should be stated that it relates to circumvent the lack of staff"

"At the end of the statement I'd add: Hospital staffing requirements should be agreed by all parties to avoid human resource shortages and compromising the safety and treatment of patients."

"It will not be easy to develop that hospital pharmacy human resource plan that fits for all European countries"

"I agree but just thinking if the role of pharmacists and hospital pharmacist shortage should be two different statements"

"But should there be own statement about staff shortages because now there are too many aspects in this statement (role of pharmacists and availability). Pharmacy staff shortage (especially in hospitals) is an important question. It should also be defined in which level we make the sustainable strategies for this (national, organisational). Do patients have right to demand/ask hospital pharmacy services? In hospital pharmacists explanation text there are some same things that in statement 7"

Comments then referred to a wide definition of "medicines":-

"I agree but I am afraid we should include also other therapeutic options based in genes in DNA fragments, even in cells, and also medical devices, and/or medical gases....not only medicines. I totally agree with the statement "to meet health needs and priorities" but it is worth to define this territory of therapeutics, even in the close future when other therapeutic options but medicines will get into the market"

"My last doubt comes from the question: It is worth a pharmacist if there is not medicine in the field? I think it is because there are other tasks related with health information, over the counter therapeutics, herbs, medicine, nutritional support,,,,all these examples doesn't include a medicine and it is worth a pharmacist...."

A comment then reflected the important issue of skill mix:-

"We would prefer a "supervision" than the "engagement of hospital pharmacists in all steps". We should delegate different tasks to pharmaceutical assistants (with specific trainings and skills), otherwise we will not manage the rise in human resources. We agree, that staff shortages should be avoided by sustainable strategies. However, The development of human resource plans should be done by the associations of hospital pharmacists in collaboration with universities, health authorities and possibly hospital administrators."

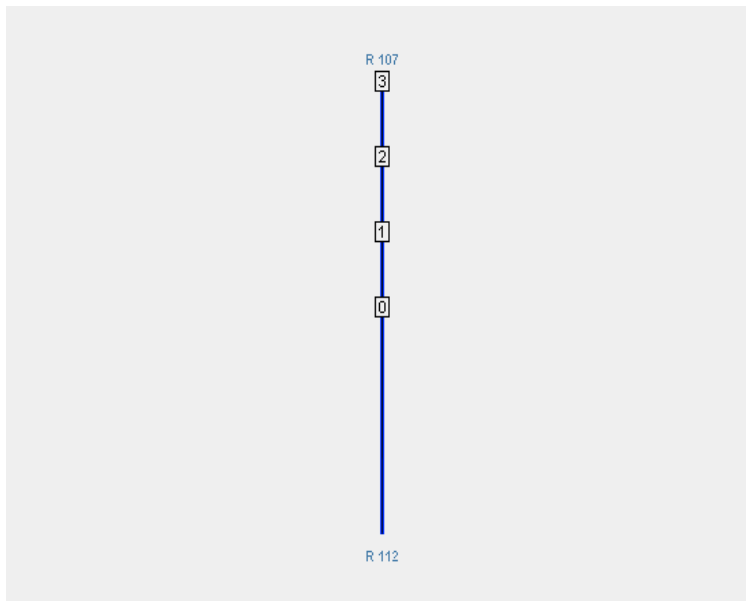
And a final point expanded the stakeholders beyond health authorities and hospital administrators and suggested a revised wording to be:-

"Associations of hospital pharmacists should develop together with universities, health authorities and hospital administrators hospital pharmacy human resource plans. These should be aligned to engage hospital pharmacists as supervisors in all steps of medicine use processes and to meet health needs and priorities across public and private sectors that optimise patient outcomes."

Conclusion: taking into account all comments, a revised statement for Delphi 2is proposed.

Hospital pharmacists should work with health authorities, hospital administrators and other locally relevant stakeholders to develop hospital pharmacy human resource plans. These should be aligned to engage hospital pharmacists as supervisors in all steps of all medicine use processes to meet health needs and priorities across public and private sectors that optimise medicines use and patient outcomes.

Partner health organisations



Average score: 3.0

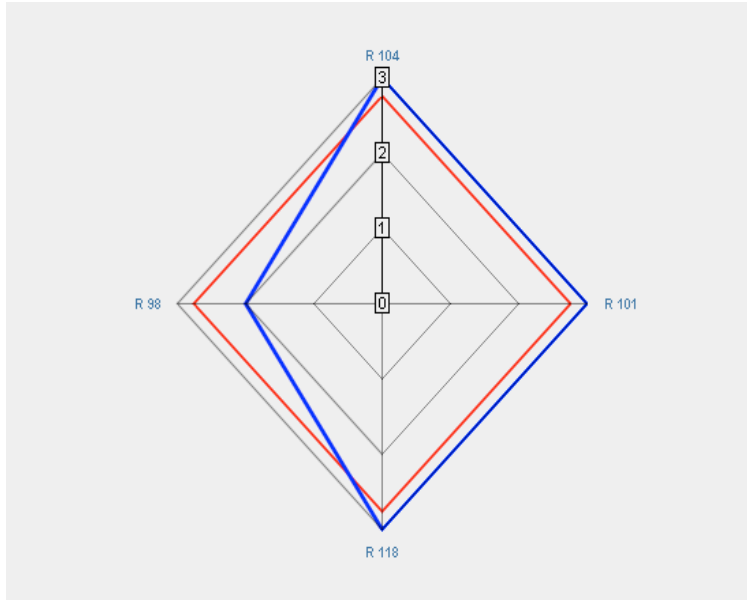
With limited responses and full agreement from partner organisations, no further amendments for Delphi 2 are required to this statement.

Action: Revise this statement for the Delphi 2 process to read:-

Hospital pharmacists should work with health authorities, hospital administrators and other locally relevant stakeholders to develop hospital pharmacy human resource plans. These should be aligned to engage hospital pharmacists as supervisors in all steps of all medicine use processes to meet health needs and priorities across public and private sectors that optimise medicines use and patient outcomes."

1.5 Hospital pharmacists must be members of Drug & Therapeutics Committees to oversee all medicines management policies and procedures, including those related to off-label use and novel investigational medicines. (Statement 5).

Patient groups

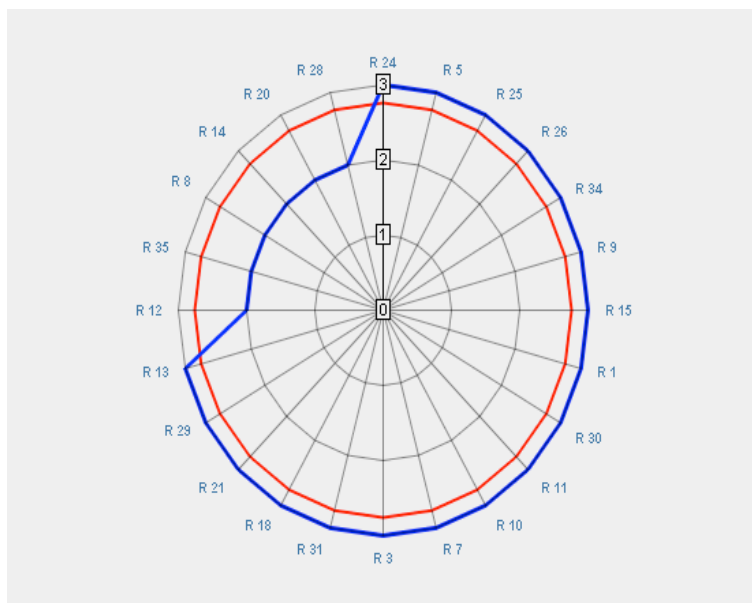


Average score: 2.75

The comment associated with the “agree” rather than “strongly agree” was supportive of the statement::

“Better knowledge will provide more patient safety.”

EAHP Members



Average score: 2.75

There were several comments referring to how Drug and Therapeutic Committees operate:-

"I am a member of D&T committee but our activity is zero."

"Firstly I would like to consider if Drug and Therapeutics Committee means the same in Europe. If we are talking of an advising committee that support de manager office in medicines management, policies and procedures then I should answer AGREE."

"not just to oversee, but also to multidisciplinary create all these policies and procedures"

"It there is also the capacity for writing down prescription restrictions, and a list of drug equivalence for doctors at hospital level , I should answer STRONGLY AGREE. If we are talking to an internal committee in an internal work group of the pharmacy then I should answer STRONGLY DISAGREE."

"rewording suggestion: Hospital pharmacists should supervise and be members of the DT committee ..."

"A suggestion to add a few words:after '...to oversee': 'and take responsibility in improving' and then continue with the rest of the sentence"

The important role of anti-counterfeit measures was then included, and after moderator encouragement, a suggestion for a revised statement:-

"Anti-counterfeit medicines strategies (MEDICRIME Convention, e-TACT) should be included in this statement as well."

Hospital pharmacists must be members of Drug & Therapeutics Committees to oversee all medicines management policies and procedures, including those related to anti-counterfeiting strategies implementation, off-label use and novel investigational medicines.

A number of additional comments reflected more specific issues which are probably best considered in later, more operationally-

related statements:-

"In addition it will be the responsibility of individual pharmacists to ensure that patients have given informed choice to the use of these medicines"

"Off-label use is one of the most heterogeneously regulated areas of medicine in Europe. It is perhaps out of the scope of this statement, but I would still advise to declare the need of harmonization in this area as well. In some countries, it is the medical authorities that decide the permission of certain off-label applications. In those scenarios, it is really hard to see the reality of the statement in question."

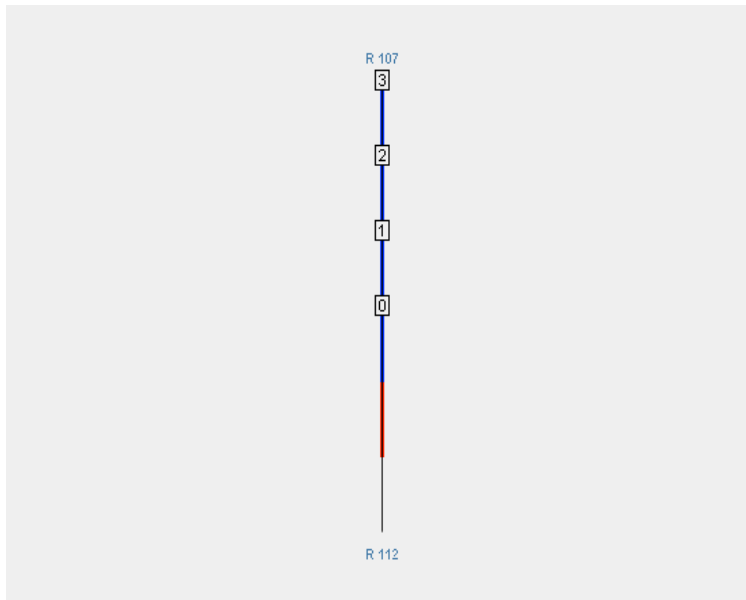
"But should our knowledge about the pharmacoeconomics be also mentioned in this statement?"

Conclusion:

This statement could be strengthened for the Delphi 2 process to define more clearly the role of Drug and Therapeutic committees:-

Hospital pharmacists should take the lead in coordinating the activities of multidisciplinary, organisation-wide Drug & Therapeutics Committees. They must be members of these Committees which should oversee and improve all medicines management policies and procedures including those related to off-label use, novel investigational medicines, and anti-counterfeit medicines strategies.

Partner health organisations



Average score: 2.0

A disagreement comment was received, which appears to be based on a misunderstanding that all hospital pharmacists should be members of the organisation's Drug and Therapeutic Committee:-

"Not necessarily all hospital pharmacists, but at least one of them working in the same hospital pharmacy."

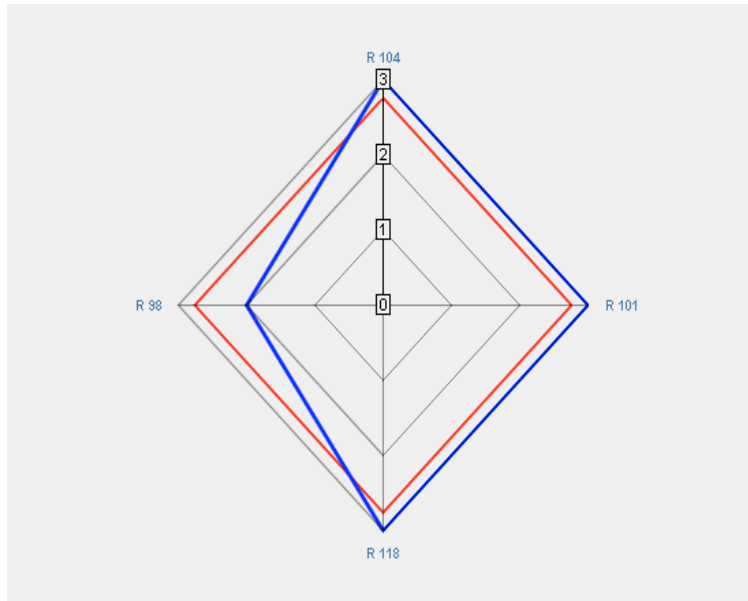
It is hoped that the revised statement will clarify this.

Action: A revised statement should be included in the Delphi 2 process:-

Hospital pharmacists should take the lead in coordinating the activities of multidisciplinary, organisation-wide Drug & Therapeutics Committees. They should have appropriate representation as full members of these Committees which should oversee and improve all medicines management policies and procedures including those related to unlicensed and off-label use of medicines, novel investigational medicines, and anti-counterfeit medicines strategies.

1.6 Hospital Pharmacists should ensure that pharmacy services are integrated within the general Information and Communication Technology (ICT) framework of the hospital including electronic health (eHealth) and mobile health (mHealth) procedures. Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes. (Statement 6).

Patient groups

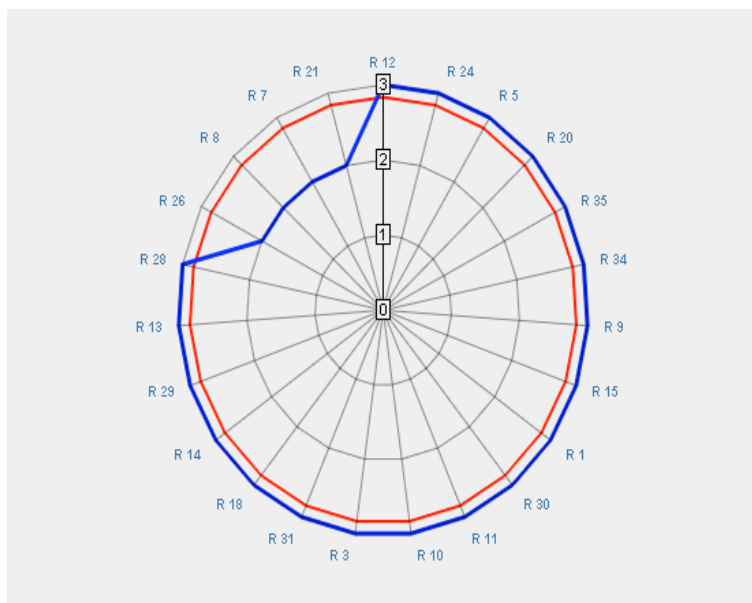


Average score: 2.75

The only comment received relating to less than full agreement referred to open access:-

"End user needs are key, and eHealth information must be available for sharing depending on roles and responsibilities."

EAHP Members



Average score: 2.75

Comments received related to operational aspects and implementation rather than any issues requiring clarification or strengthening of the statement:-

"Our hospital pharmacists have knowledge but our hospital did not have implemented ICT"

"This aspect should be considered regarding the university and advanced/continuing education."

"As the hospital pharmacist is a user of those technologies and as responsible for patient safety in medicines, he absolutely must be involved in the design and integration of those processes. Don't forge that an Hospital Pharmacy is the center of informations for all the people (patients, nurses, doctor's, pharmacist's..)"

"This might not be related, but it should be emphasised that ICT framework should take into account 'data confidentiality'."

"Hospital pharmacists intervene in the medication use process in several steps, starting with perceived need for a particular drug for a patient and ending with the monitoring and evaluation of its effectiveness in patients. Therefore, they are key elements and must be evolved in the design, specifications of parameters and evaluation of information technology and information systems within the medicines process."

"The healthcare professionals explanation text is not in line with the statement (different meaning and content in statement and explanation)! Pharmacy services integration is missing from explanation texts."

"I would rewrite Hospital pharmacists text to: "Modern advances in ICT technology can improve patient safety regarding medication us and this should be promoted by hospital pharmacists. For this reason hospital pharmacists should be involved proactively in the planning...."

"I should propose to define a minimum level for considering pharmacy services integrated within the general information and communication technology. After we can approve this statement."

"Which is the minimum level to consider integration: prescription only, prescription plus logistics, prescription plus logistics plus drug preparation, prescription plus logistics plus drug preparation plus clinical interventions.....????"

"The minimum level - all you have mentioned. It's essential."

"Changes within the pharmaceutical curriculum are necessary if the pharmacists will be able to participate on an equal level with other IT-professionals."

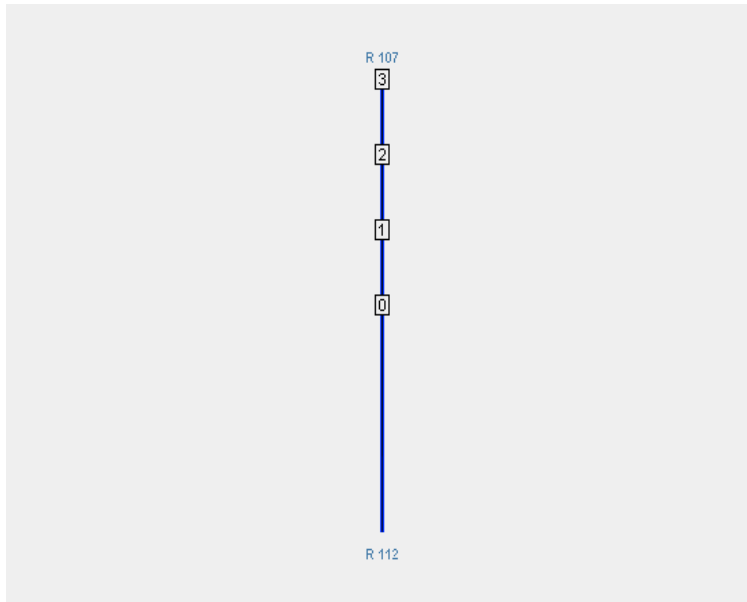
"The key message of this statement is by all means to be supported. Heterogeneity, however, is also a major issue here. Member states show so many different phases of readiness for eHealth procedures that it is nearly impossible to form a statement ubiquitous"

enough without it being too vague or broad.”

Conclusion: No change to this statement for Delphi 2 process.

Hospital Pharmacists should ensure that pharmacy services are integrated within the general Information and Communication Technology (ICT) framework of the hospital including electronic health (eHealth) and mobile health (mHealth) procedures. Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes.

Partner health organisations



Average score: 3.0

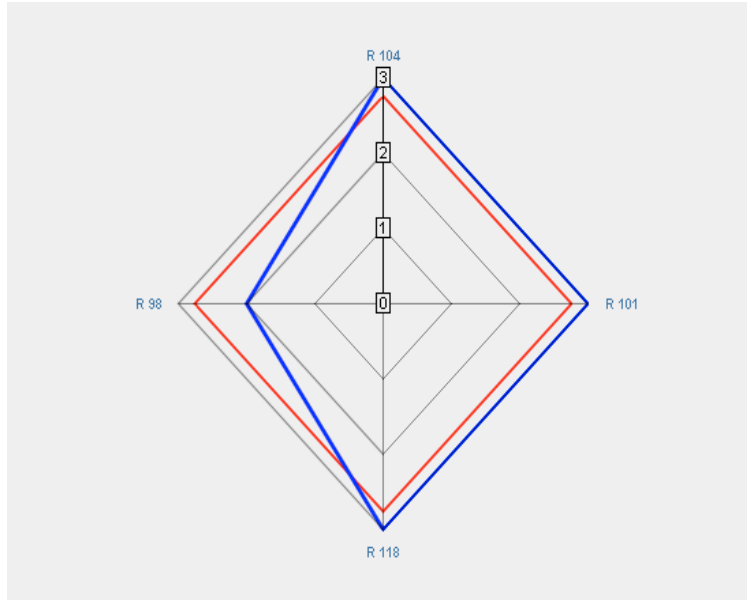
No comments were received from partner health organisations which indicate a need to revise this statement.

Action: Statement to proceed to Delphi 2 with no changes.

Hospital Pharmacists should ensure that pharmacy services are integrated within the general Information and Communication Technology (ICT) framework of the hospital including electronic health (eHealth) and mobile health (mHealth) procedures. Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes.

1.7 Hospital pharmacists should develop, together with other healthcare professionals, criteria in order to focus the activities of the Hospital Pharmacy ensuring optimal outcomes for patients. Health systems have limited resources and these should be used responsibly. (Statement 7).

Patient groups



Average score: 2.75

Relevant comments received were:-

"in order to prioritise most efficiently and effectively - a multidisciplinary discussion and decision is needed"

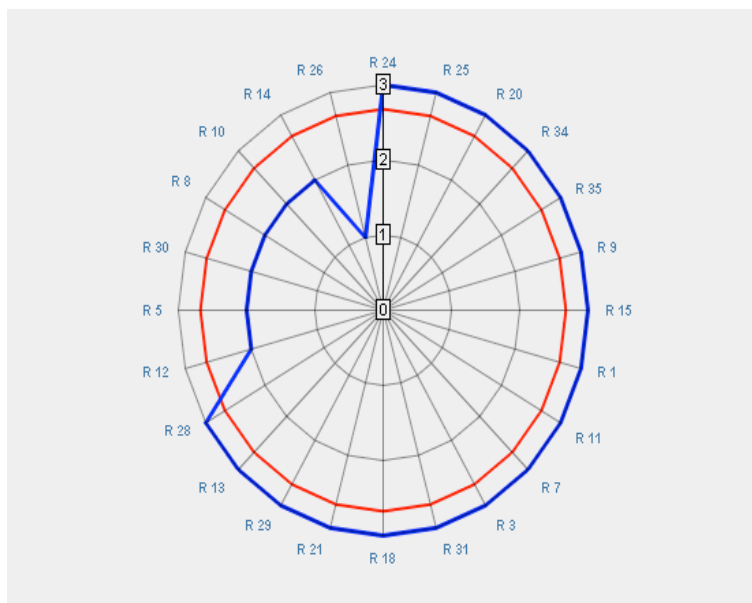
"Also patients' groups should be included in the development"

"This would be very valuable in regard to advice and information beyond the use of medicines, eg. for lifestyle changes".

Conclusion: the statement can be reworded to strengthen and clarify the involvement of stakeholders.

Hospital pharmacists should develop, in collaboration with other stakeholders which include other healthcare professionals, patients and the public, criteria to enable the prioritisation of the activities of the hospital pharmacy. Health systems have limited resources and these should be used responsibly to optimise outcomes for patients.

EAHP Members



Average score: 2.67

Most comments were supportive, and in line with a strengthening of the stakeholder element of this statement.

"Strongly agree, prioritisation of hospital pharmacy activities should be decided together with other healthcare professionals whose point of view is very important in order to define the value of these activities for patients and stakeholders. I would actually replace optimal outcome by optimal value"

"optimal outcomes for patients as we talk about the use of medicines can only be achieved with a multidisciplinary approach People and Systems must work together in a seamless way"

"replace "maximum outcomes" by" maximum impact" or "best outcomes""

This statement I agree is very related with specialisation. That means that I strongly agree if we talk about hospital pharmacy specialist.....It we talk about pharmacist I do not agree because there is other profession called clinical pharmacologist (this is a specialisation mark from doctors) and we share the same task : to ensure optimal outcomes for patients, and it is not easy to be at the same level if hospital pharmacist is not consider a specialisaton process from pharmacy degree

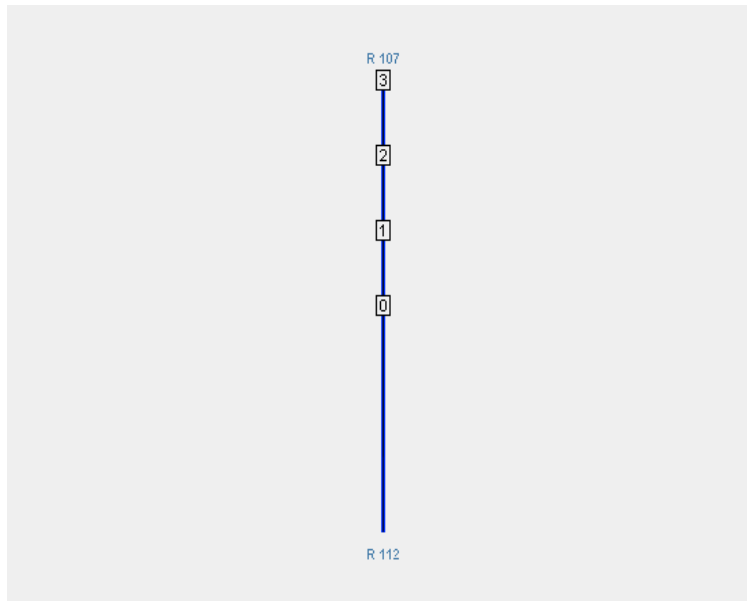
I disagree only because I don't quite understand the meaning for this statement. If other healthcare professionals/administrators thinks that logistics is most important for patient outcomes, do we quit doing clinical pharmacy services? What is irresponsible use of pharmacists resources? In some sentences statement 4 and 7 are repeating each other...

Statement 4 refers to human resource palnning; this statement 7 refers to task / role prioritisation (once the resources are agreed); there are never sufficient resources to do everything

Conclusion: revised wording for this statement should proceed to Delphi 2 process.

Hospital pharmacists should develop, in collaboration with other stakeholders which include other healthcare professionals, patients and the public, criteria to enable the prioritisation of the activities of the Hospital Pharmacy. Health systems have limited resources and these should be used responsibly to optimise outcomes for patients.

Partner health organisations



Average score: 3

Full agreement from partner health organisations on this statement.

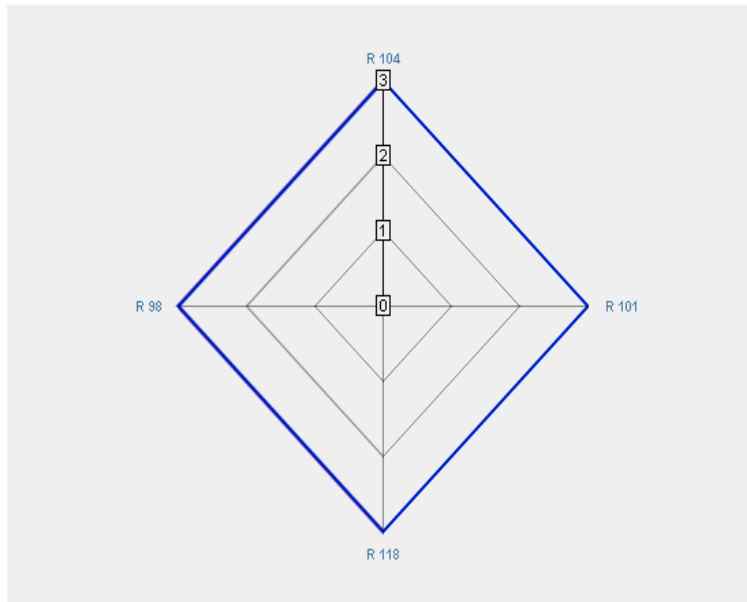
Action. Revised wording to proceed to Delphi 2 process.

Hospital pharmacists should develop, in collaboration with other stakeholders which include other healthcare professionals, patients and the public, criteria to enable the prioritisation of the activities of the Hospital Pharmacy. Health systems have limited resources and these should be used responsibly to optimise outcomes for patients.

Aspect: Selection, Procurement & Distribution

2.1 Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital pharmacists should establish procedures of procurement based in principles of safety and quality of medicines according to the best practices and in line with national legislation. (Statement 8).

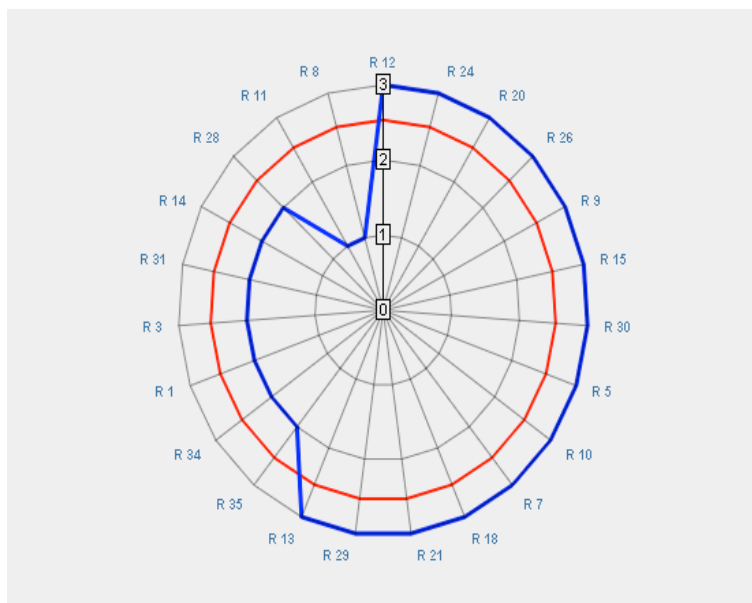
Patient groups



Average score: 3

Full agreement on this statement from patient groups.

EAHP Members



Average score: 2.52

Some comments wanted procurement to extend to medical devices, whilst other comments seemed to indicate difficulties with this proposal:-.

"What about medical devices? I think that, in addition to pharmaceuticals, the medical devices should be added".

"I can also comment this - yes, in our country the pharmacists also procure medical devices. At the university we had the optional classes in MD, we have a baccalaureate degree and for the assistants we have the specialisation in MD."

"Yes, hospital pharmacists must procure medical devices, however in my opinion we don't get appropriate training in this area."

"And we also ask for implementing the certificate in MD for pharmacists into our legislation and re-establishing the authorization for wholesalers of medical devices".

It appears that training in medical devices and therefore the responsibilities for procurement may be different across member countries. It may be best to leave the statement as it stands in this respect and debate at Barcelona.

Further comments raised the importance of transparent procedures.

"The hospital pharmacist must have a key role in defining the specifications of procurement. Also, transparency is vital here, so I would strongly advise that it appeared somewhere in our statements".

"transparent procedues; in line with national and/or European legislation"

And yet another theme in comments was personal responsibility for procurement. Some comments seemed sometimes not to recognize that the proposed statement is about hospital pharmacists creating appropriately robust procedures (processes), and not necessarily personally undertaking the procurement.

"The procurement of pharmaceuticals is the task of the hospital pharmacist, but the selection (safety/quality/scientific requirements) of the pharmaceuticals must be done in collaboration of all the members of the Drug and Therapeutic Committee".

"Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital pharmacists should establish procedures of pharmaceutical procurement, undertaken solely by hospital pharmacies, based in principles of safety and quality of medicines according to the best practices and in line with national legislation".

"this is a overall responsibility of a pharmacist but may be better delegated to other pharmacy professionals"

"If any medicine is authorised by EMA or National Drug Agency - that means it is safety and quality. Then procedures of procurement only depend of national legislation".

*"Suggestion: Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital pharmacists should establish procedures of procurement based in principles of safety and quality of medicines **and medicine usage** according to the best practices and in line with national legislation"*

"Procurement of pharmaceuticals should not be a core activity of a hospital pharmacist. At the moment it might look like that in the majority of countries. However, it could be said that pharmaceutical medicine management (including procurement) is a core activity of hospital pharmacists."

"Agree with this clarification of procurement being one component of medicines management"

Procurement is related with logistics. Sorry if I do not understand the term in English.

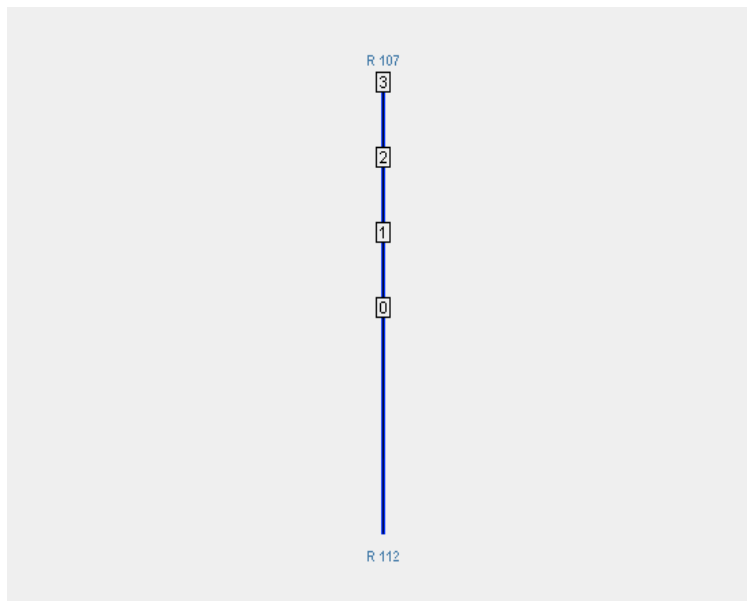
"Logistics is a complex process but it is linked mainly with national legislation ...is very administrative....."

"Procurement I think is related with drug easy handling, good description of contents, good packaging and good price.....In fact generics is the first option if the fit with standards in packaging. So I would say procurement actually is price managed, and as I said very administrative."

Conclusion: taking all comments into account, it is suggested that the following revised wording proceed to the Delphi 2 process.

Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital pharmacists should establish transparent procurement processes based on principles of safety and quality of medicines, in line with best practice and national legislation.

Partner health organisations



Average score: 3

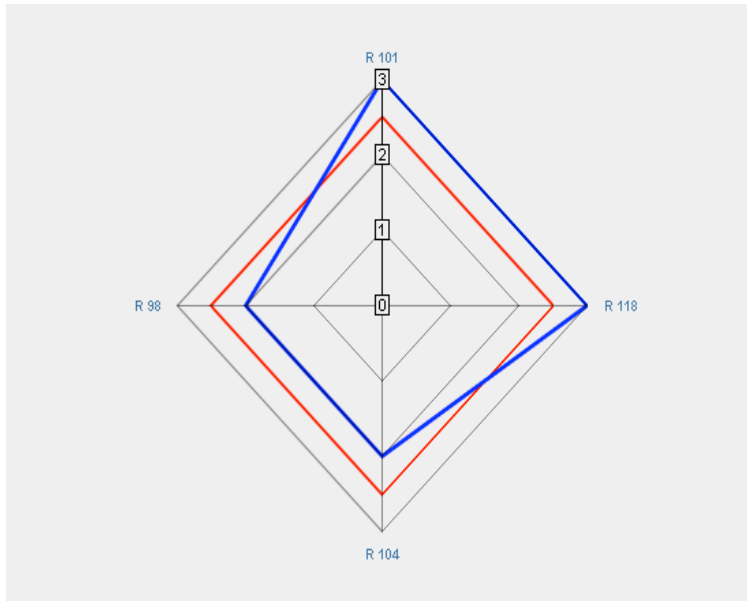
No additional substantive comments received from Partner Health organisations.

Action: revised statement to proceed to Delphi 2 process

Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital pharmacists should establish transparent procurement processes based on principles of safety and quality of medicines, in line with best practice and national legislation.

2.2 Hospital pharmacists should have responsibility regarding the management of medicine use processes and medicine related technologies. (Statement 9).

Patient groups



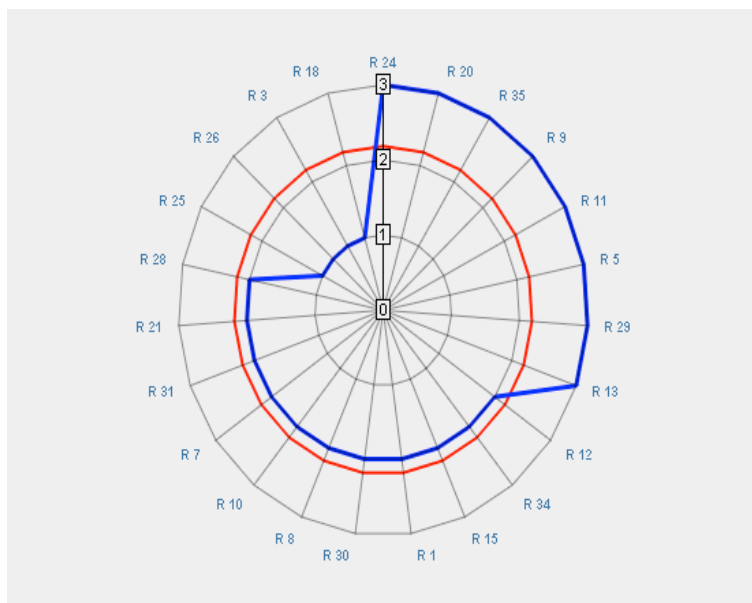
Average score: 2.5

Two comments reflected whether the responsibility was shared with others.

"a part of the responsibility regarding ... "

"At least they should be involved in the management process".

EAHP Members



Average score: 2.17

Comments about this statement varied, but generally reflected that shared responsibility had a place, and in addition that the statement required some clarification.

"They have responsibly regarding the management"

"Hospital pharmacists should have responsibly in drug and medication related devices selection/ management in order to ensure its appropriate quality"

"Hospital pharmacists should have a shared responsibility with the other health care professionals concerning the management of medicine use processes and medicine related technologies. The hospital pharmacists are the end decision makers in this activities because the safe use of medicines is their core business"

" 'Should have responsibility' should be changed to 'should have clear and outlined responsibilities'."

"Hospital pharmacists should have responsibility regarding the management of medicine use processes and medicine related technologies - only for those directly under their care. Once a product leaves the Pharmacy Department and received by the destined ward or department it becomes the responsibility of that ward or department. At this point Pharmacists can only advise."

"There should be inserted "shared" responsibility."

"The medicines management is a 'care process' and should be aligned with all other processes of the hospital.2"

"Statement should be revised: Hospital pharmacists should as an expert have a big impact in the design of the management of medicine use processes and medicine related technologies in order to optimize patient safety and outcome of therapy = Medicines Optimization"

"Hospital pharmacist should have a shared responsibility in this area."

*"Hospital pharmacists should have responsibility for the management of medicine **distribution**, processes and medicine related technologies."*

"don't understand, do you mean should have responsibility ?"

"Medicine use process and medicine related technologies are not the same thing and the impact of pharmacists in those is different so I think that the process and the technologies should have own statements.2"

"I agree that pharmacists have important role when planning to have new medical devices and implementing their safe use in medication process, but the responsibility of devices quality and authorisation is in technical department."

"In healthcare professionals explanation text the last sentence (having a clear line for...) is not needed or if you will have it, please"

add nurses concerns.”

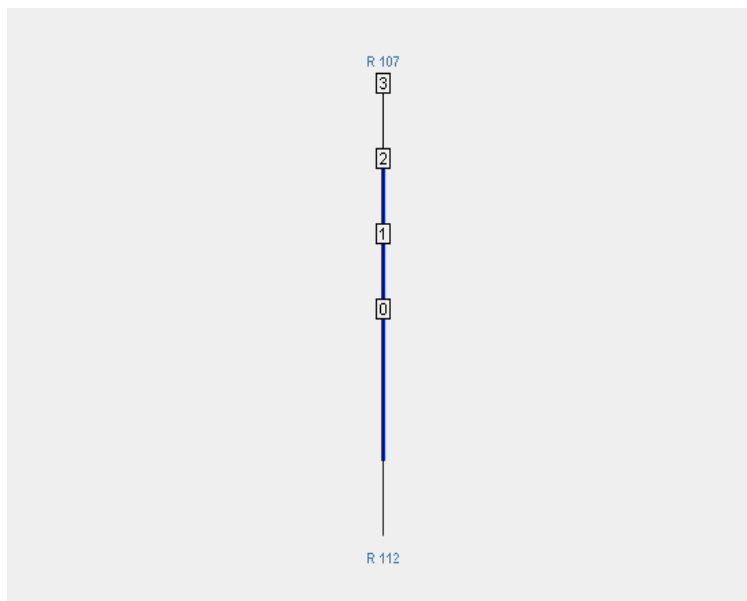
“there are other professionals that deal with medicines devices like pumps and administration sets”

It might be hard to manage processes of medicine related technologies because not in all countries pharmacists are responsible for that”

Conclusion: taking all these comments into account, it is suggested that the statement be revised for the Delphi 2 process to reflect in particular the shared responsibility:-

Hospital pharmacists should take the lead in developing, monitoring, reviewing and improving medicine use processes and processes for the use of medicine related technologies. Responsibility for such processes and their use should be clearly defined, and may vary according to the medicine, the medicine related technology, the health care setting and the multidisciplinary team delivering care.

Partner health organisations



Average score: 2

Again, there were comments about this being a shared activity with others and other professional groups.

“In EU nations there are qualified specialist nurses with prescribing authority and I’m not sure if this aspect need to be added in one of this or other the statements. So not going for disagree or strong disagree but make a mark for attention.”

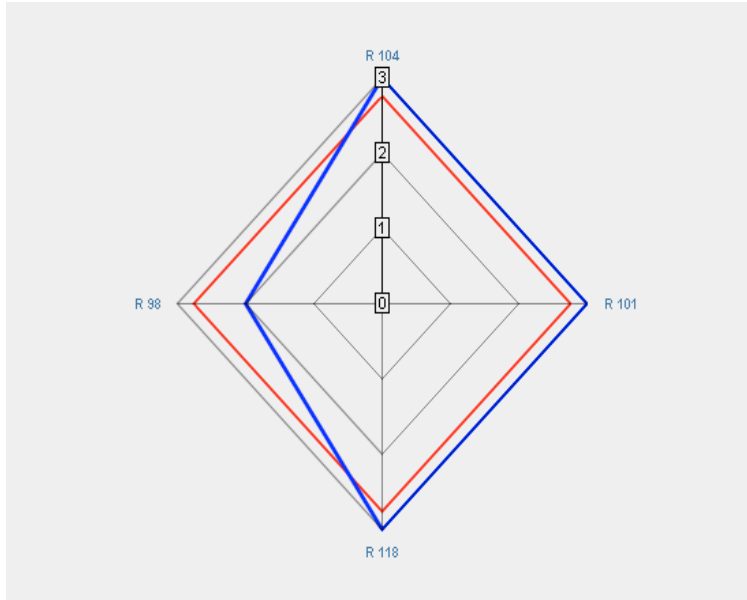
“In collaboration with health care professionals”

Action: revise statement for Delphi 2 process:-

Hospital pharmacists should take the lead in developing, monitoring, reviewing and improving medicine use processes and processes for the use of medicine related technologies. Responsibility for such processes and their use should be clearly defined, and may vary according to the medicine, the medicine related technology, the health care setting and the multidisciplinary team delivering care.

2.3. Hospitals should utilise a medicine formulary system, local regional and/or national. The medicine formulary system should be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence. (Statement 10).

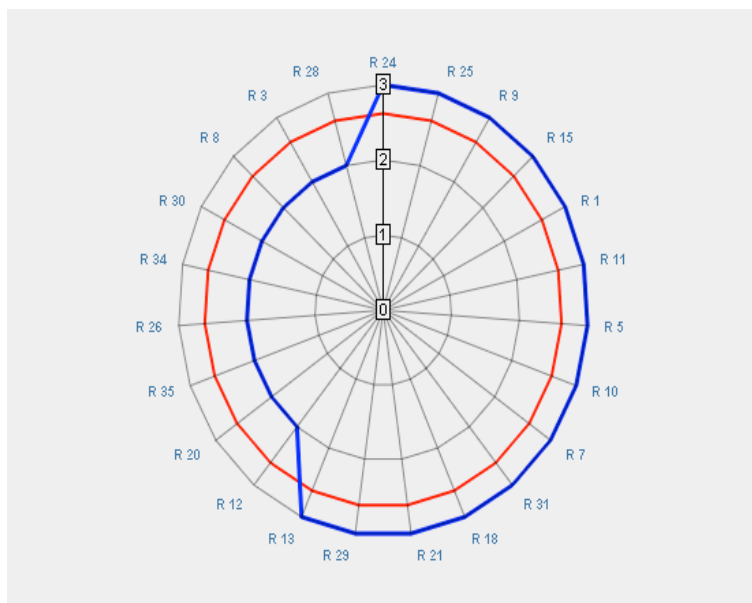
Patient groups



Average score: 2.75

No significant comments were received from patient groups on this statement.

EAHP Members



Average score: 2.61

Comments again mentioned devices.

Would it be possible here to mention medical devices?

I think that medical devices should not be forgotten as their usage plays an important role in terms of health outcomes (quality of medical devices). If I'm not mistaken but Health Technology Assessment (HTA) could be used for "some form of rationalisation of medical devices usage" that you mentioned.

Most comments were supportive and suggested or indicated the need for minor amendments:-

"this is very important a should be a European standard"

"should implement and utilise ... "

"on the best available evidence regarding efficacy, safety and cost-effectiveness."

"It is a must that in a hospital there is a medicine formulary system, but I want to mention the aspect of safety too in the choice of medicines on that formulary"

"We have only national formulary system"

"Medicine formulary system or even better therapeutics formulary system is the basement for procurement. Hospital pharmacy system is the first step to establish a good clinical practices evidence based activities.2"

A revised statement was provided in one comment:-

Hospitals should utilise a medicine formulary system, local regional and/or national. The medicine formulary system should be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence including patient outcomes and pharmacoeconomic evaluations.

Finally one comment asked whether statements 10 and 11 could be combined.

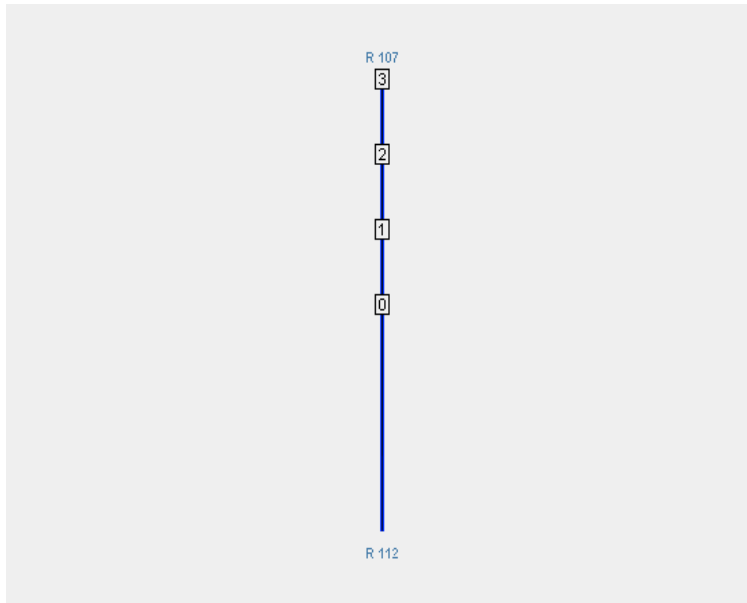
"Focus statement 10 and 11 so that there is no repetition about the formulary in both statements or can these two statements be integrated."

On balance for Delphi 2, separate statements have been retained.

Conclusion: Taking all comments into account the following revised statement is proposed for the Delphi 2 process:-

Hospitals should develop, maintain and use a medicines formulary system, which may be local, regional and/or national. The medicine formulary system should be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence including patient outcomes and pharmacoeconomic evaluations where these are available.

Partner health organisations



Average score: 3.0

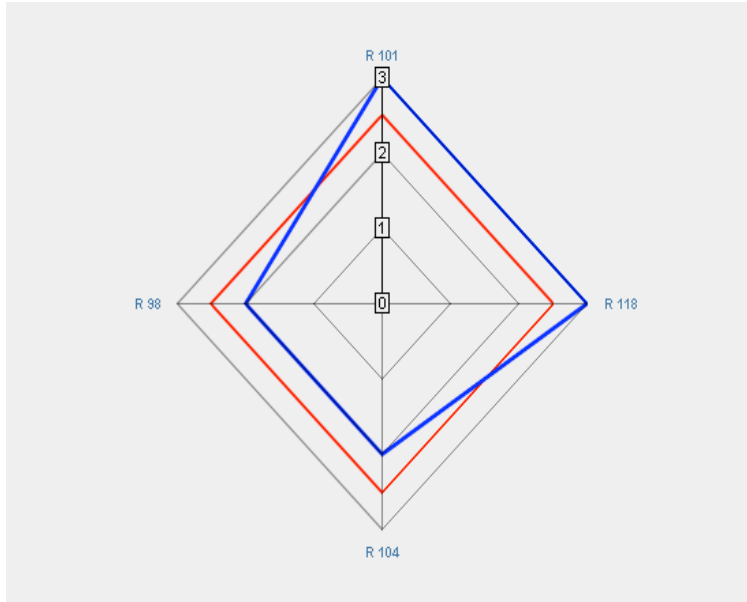
No significant comments were made by Partner Health Organisations.

Action: the revised statement is proposed for the Delphi 2 process:-

Hospitals should develop, maintain and use a medicines formulary system, which may be local, regional and/or national. The medicine formulary system should be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence including patient outcomes and pharmacoeconomic evaluations where these are available.

2.4 Procurement must be according to the medicine formulary and informed by the formulary selection process. (Statement 11).

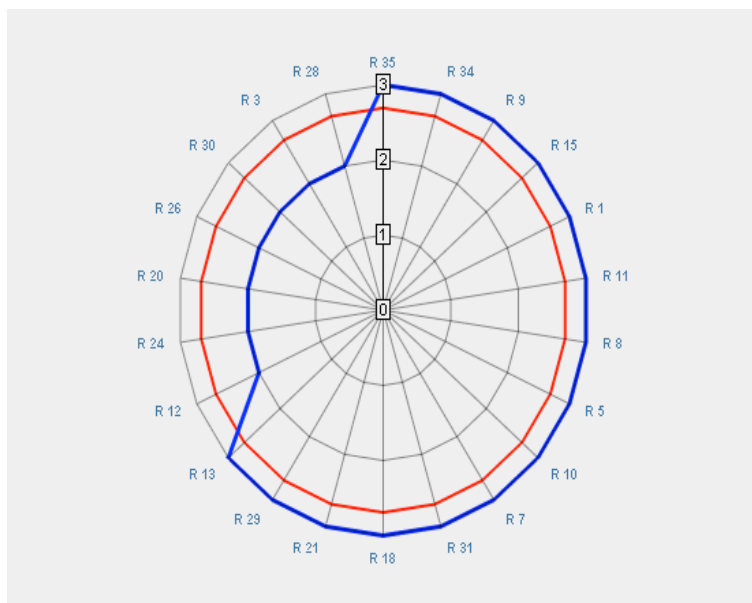
Patient groups



Average score: 2.5

No significant comments were made by Patient Groups.

EAHP Members



Average score: 2.68

Most comments were supportive, with the need for off-formulary procurement being identified.

"First therapeutic formulary process and after procurement. This is the way"

"The statement is correct and sufficient, no more comment.2"

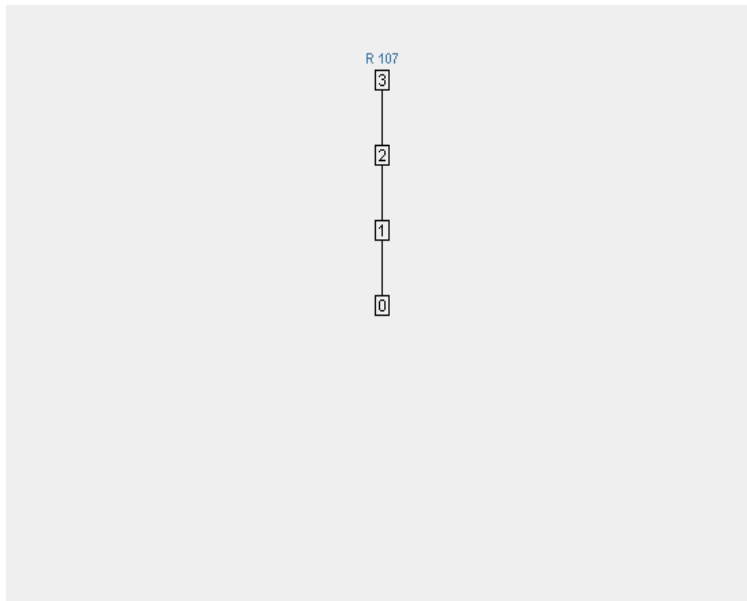
"there should also be a pathway to procure medicine NOT in the formulary"

"provided this is not a barrier to the effective treatment of patients and appropriate access to non-formulary drugs"

Conclusion: the issue of off-formulary procurement is probably important enough to suggest a revised statement for the Delphi 2 process.

Procurement should usually be according to the medicine formulary and informed by the formulary selection process. A robust process should also be in place to appropriately procure medicines not included in the formulary where their use is indicated for the safe and effective care of individual patients.

Partner health organisations



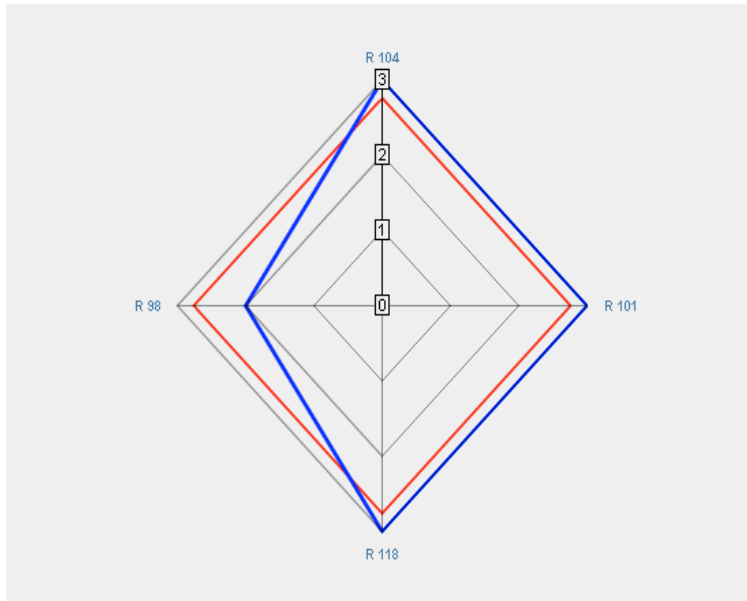
No significant comments were made by Partner Health Organisations.

Action: a revised statement for the Delphi 2 process is proposed:-

Procurement should usually be according to the medicine formulary and informed by the formulary selection process. A robust process should also be in place to appropriately procure medicines not included in the formulary where their use is indicated for the safe and effective care of individual patients.

2.5 Each hospital pharmacy should have contingency plans for shortages and purchases for medicines and all products under its responsibility. (Statement 12).

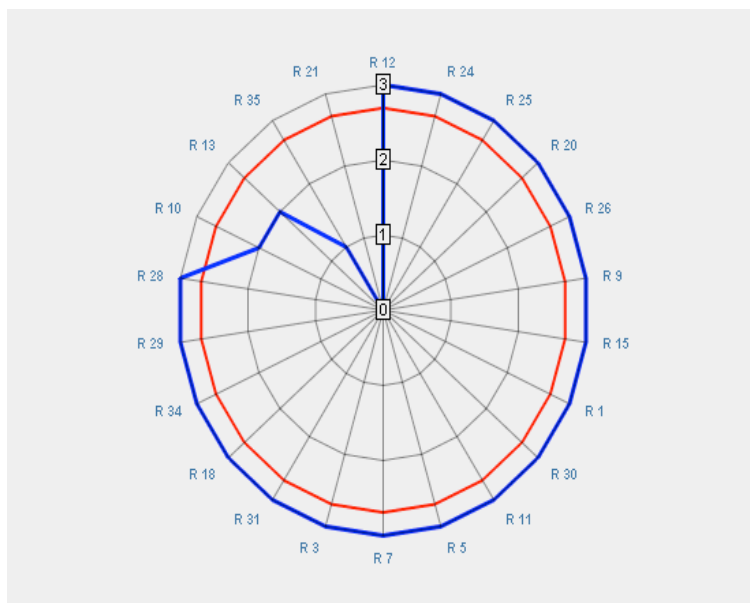
Patient groups



Average score: 2.75

No significant comments were made by Patient groups.

EAHP Members



Average score: 2.68

Medical devices appeared again as a comment.

"What about medical devices? I think that, in addition to pharmaceuticals, the medical devices should be added."

Other comments reflected the role of other organisations in managing medicines shortages:-

"These plans are created, implemented and supported by hospital pharmacies and national health authorities."

"I agree, but those contingency plans must be assisted by the national authorities, because the national Health organisations must also assure that treatments for patients are not disturbed by too frequent shortages due to economic reasons."

"This should be the role of either the management, pharmaceutical companies, the distributors, and the healthcare authorities. Also, the issue should be addressed on national, regional, or even EU-levels."

"the medicines shortages due to periodic lack of funds is not our responsibility. Some medicines shortages are due to market ruptures that are not informed in time; therefore, companies should be responsible also. never the less, a contingency plan must exist."

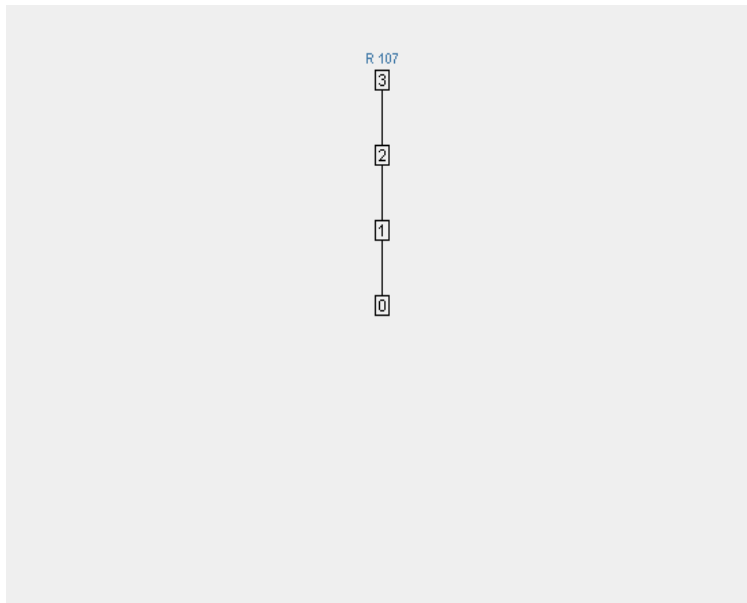
One comment suggested contingency plans only for essential medicines.

"In my opinion there should be contingency plans only for essential medicines, you can't have plans for all drugs in the formulary. So you have to prioritize."

Conclusion: taking all the comments into account a small change in this statement is proposed for the Delphi 2 process:-

In collaboration with other local and national health organisations, each hospital pharmacy should have contingency plans for shortages of medicines, and for other health care products which it procures.

Partner health organisations



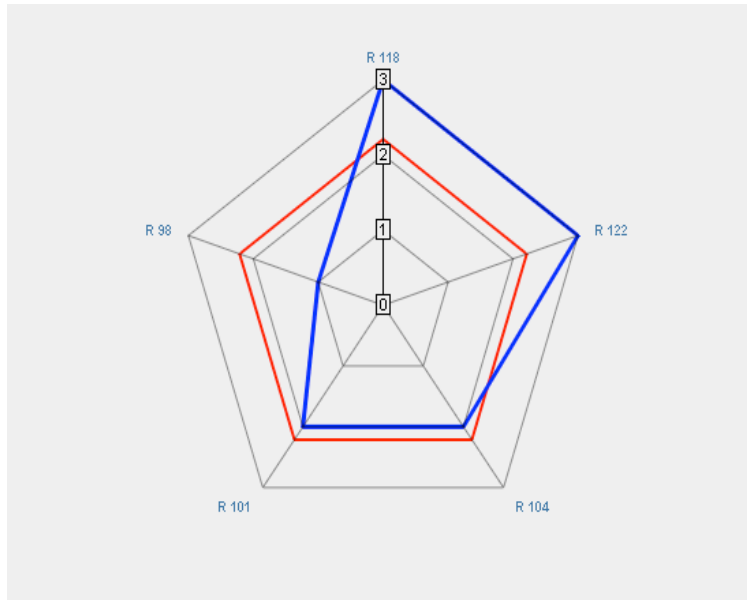
No significant comments were made by Partner Health Organisations.

Action: the following statement is proposed for the Delphi 2 process:-

In collaboration with other local and national health organisations, each hospital pharmacy should have contingency plans for shortages of medicines, and for other health care products which it procures.

2.6 Hospital pharmacy departments should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, and distribution conditions for all medicines and pharmaceutical products used in the hospital, including investigational medicines. (Statement 13).

Patient groups



Average score: 2.2

A specific comment was made relating to haemophilia care:-

"In some countries medicines for treatment of hemophilia and related bleeding disorders are traditionally stored and distributed by blood banks and transfusion medicine centers, even though the latest generations of products require less stringent conditions. In other countries the latest treatment products are either already stored and distributed by hospital pharmacies or such mode of management is considered and intended to be implemented. Such reorganization may be potentially damaging for the quality of hemophilia care due to many reasons, including infrastructural unpreparedness of pharmacies, requirement for additional training, unwillingness to accept the new role, fear of unprofitability etc.

*Therefore, to minimise the potential negative impact on patients quality of life and to facilitate the reorganization process where applicable, we propose the following addition to the above **"In the event when hospital pharmacy is expected to take over the storage and distribution of medicines from another entity (e.g. blood bank and transfusion medicine unit), it is bound to accept the new responsibility. Hospital pharmacy department cannot permanently refuse to take over when such medicines are life-saving and patients cannot quickly access them via other distribution channels. In such cases hospital pharmacies should implement necessary adjustments to infrastructure unless adequate facilities or arrangements are already in place for the storage and distribution of medicines in question."***

Whilst this is clearly a significant individual issue, the statement as it stands would mean that the hospital pharmacy would necessarily assume responsibility. On balance it would seem to be disproportionate to add a specific detailed statement when the implementation of the proposed statement resolves the issue.

Other comments related to investigational medicines.

"Partially agree. Investigational medicines should only/also be the responsibility of study investigators."

"Are study investigators always able to store and prepare investigational medicines correctly without the expertise of hospital pharmacy departments?"

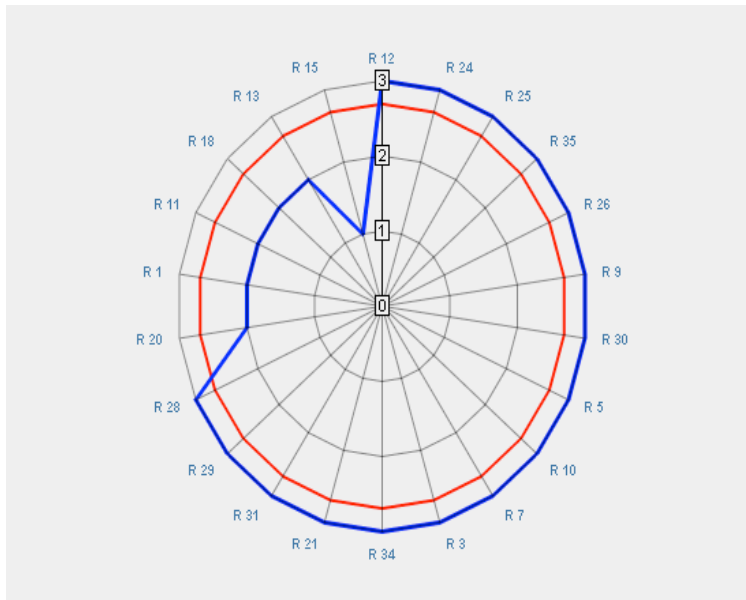
“some doubts about investigational medicine”

On balance, the pharmacy and its staff are likely to be the appropriate place and people to correctly store and supply as appropriate investigational medicines and it is not proposed to revise the statement in this aspect for the Delphi 2 process.

One comment felt that this was a joint responsibility:-

“I think this should be a shared responsibility between HPs and operations management.”

EAHP Members



Average score: 2.68

Two comments related to a lack of direct responsibility in some circumstances:-

*“Hospital pharmacy departments should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, and distribution conditions for all medicines and pharmaceutical products used in the hospital, including investigational medicines, **but only whilst under their care. Once officially handed over to the ward or department destined for then the storage becomes the responsibility of that ward or department the Pharmacist can then only advise.**”*

“Hospital pharmacy departments should not have responsibility for the logistics in the hospitals when they are not a part of the same business unit as the hospitals. This is the case in Norway where the hospital pharmacies are organised as independent business units within the regional health trusts.”

It is proposed not to amend this statement for the Delphi 2 process. Pharmacists have a duty of care and if they are aware of inappropriate logistics in another part of the same building they should still take appropriate action as the medicines expert to ensure patient safety is not compromised by potentially inappropriate logistics.

Other comments were:-

“But I’ve read the statement of the national authority (not in our country) that the pharmacist is not responsible for storage of the investigational medicines cause it is not stated or defined in GCP guidelines.”

No revision is proposed in this respect for Delphi 2 (see Patient groups text.)

“what about radioactive isotopes, medicines used for imaging etc - should this be stated especially also ?”

No revision is proposed in this respect for Delphi 2; the text covers such products.

“Among proper storage, preparation, dispensing, and distribution conditions for all medicines and pharmaceutical products, hospital pharmacy departments should have available “proper anti-counterfeit mechanisms” as well.”

This is covered in a previous statement. No revision proposed.

Agree in ideal situation. But quite often there is lack of pharmacists in hospitals to do this

I agree, but in order to fulfill the statement, standards in terms of procedures and number of pharmacists and technicians under pharmacist direction should be defined, considering the level of care performed. if a pharmacy has low human resources and little automatization it might be difficult to fulfill the statement.

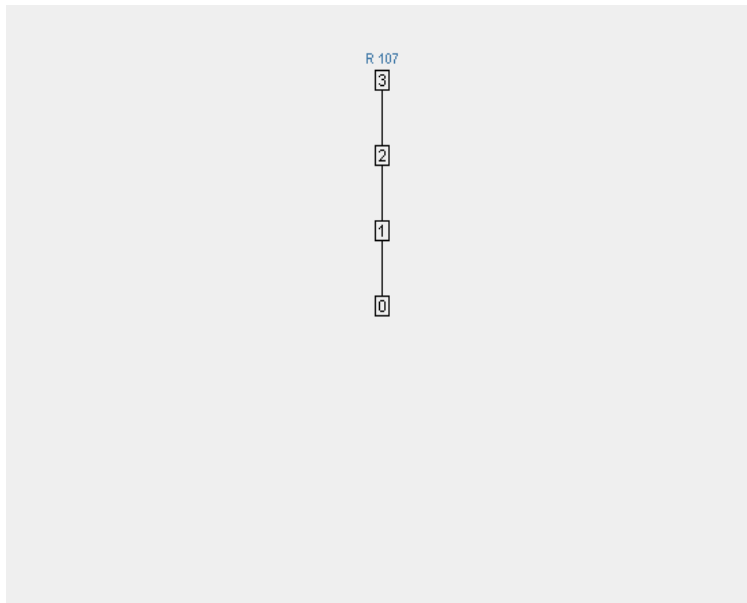
As part of the hospital administration, pharmacists should decide upon the quality criteria that distributors of medicines have to comply with. The HP department thus sets the standards of the logistics

Again, none of the comments indicate a need to amend the statement.

Conclusion: statement is not amended for Delphi 2.

Hospital pharmacy departments should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, and distribution conditions for all medicines and pharmaceutical products used in the hospital, including investigational medicines

Partner health organisations



No significant comments were received from Partner Health organisations.

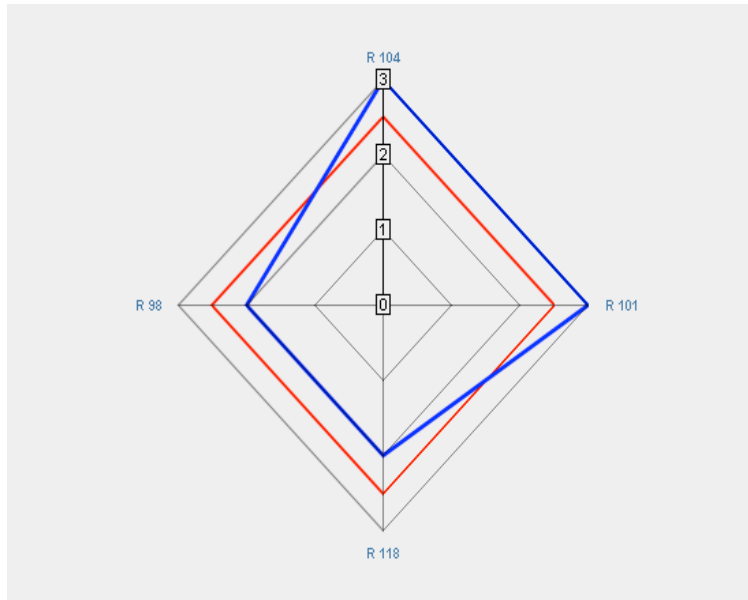
Action: statement is not amended for Delphi 2:-

Hospital pharmacy departments should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, and distribution conditions for all medicines and pharmaceutical products used in the hospital, including investigational medicines

~

2.7 Hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients, by evaluating the appropriateness of all medication including herbal and dietary supplements. All the medicines brought by patients should be registered on the medical record confirmed by the hospital pharmacist. (Statement 14).

Patient groups



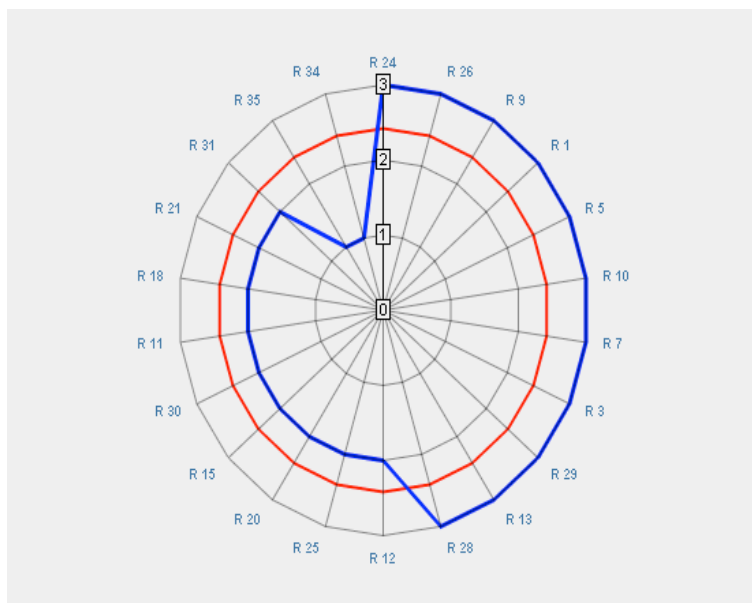
Average score: 2.5

One comment indicated a shared responsibility:-

“Support yes, but this isn’t only the responsibility of the HP.”

However, the statement does not indicate that medicines reconciliation on admission is the sole responsibility of hospital pharmacists. No amendment is required.

EAHP Members



Average score: 2,41

This statement required some clarification as it seems to cover both use of patients own medicines in hospital and medicines reconciliation.

"here clarification is needed: is the statement about fostering to use patients' own drug in the hospital, in order to avoid changes and even safe money in the hospital? This is not allowed in my country, as the drugs outside the hospitals are paid by someone else. Or is the statement about assuring a complete medication history in order to avoid loss of information and to get a complete overview?"

"yes and there are many differences between countries - for example in UK patients are encouraged to bring their own meds in hospital for use and in France this is forbidden"

"PODs - patients own drugs - is a well known term - can this be used instead"

"Confirmed by the hospital pharmacist or the pharmacy technician (supervised by the hospital pharmacist)"

"I support the statement, but it will not be applicable in countries where patient's own medicines by law are not supposed to be used in the hospitals, eg in Norway. A comment should be made on this eg under "Information". "

"This policies should include co-operation between public and hospital pharmacists via seamless care medical records systems."

"Currently it is impossible because there are no enough pharmacists to do this"

"This is another typical example of how heterogeneous our profession's legislative background is in the EU. In many countries, it is not allowed for patients to bring their own medicines into the hospitals. In some of these countries, they still do it anyway."

"Yes, it would be ideal to have them reviewed by the hospital pharmacies, although I don't really see how could we cope with the increased workload without proper human resource background."

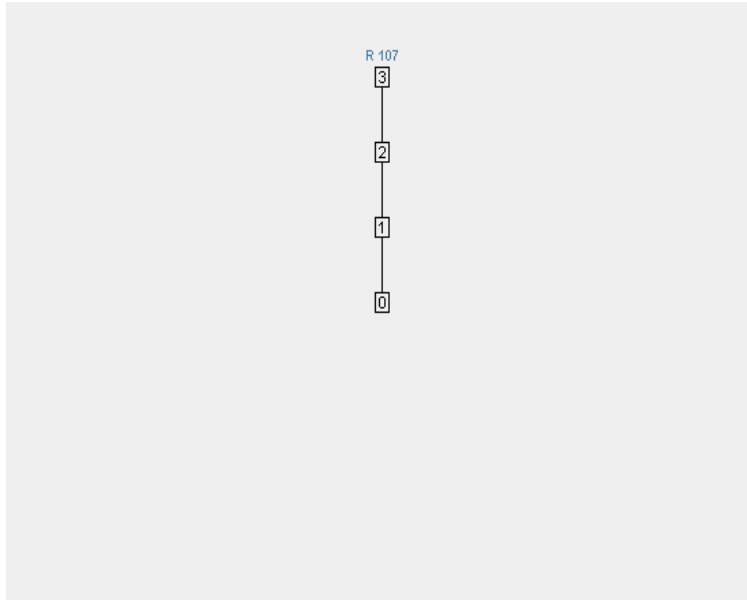
"Hospital pharmacists should indeed support the development of policies regarding the use of medicines brought into the hospital by patients. in those policies must be mentioned in which way the Best Possible Medication History will be obtained and once that BPMH is obtained, the doctors start the hospital therapy and then they must evaluate the appropriateness of the BPMH. It is true that hospital pharmacists can take part to the medication reconciliation process that can start at the moment the hospital therapy is prescribed. But in a medication reconciliation process, only the medications that are on the BPMH are evaluated. There is no need to evaluate the appropriateness of medications brought to the hospital that have not been obtained in the BPMH. Patients can bring into the hospital medications of their partner, or medications that have been stopped a long time before."

"Must the BPMH obtained be confirmed by a hospital pharmacist or is it the task of the doctor in the hospital who treats the patient, because BPMH can also be obtained by nurses, or by pharmaceutical assistants or by doctors?"

Conclusion: an amended statement is proposed for the Delphi 2 process:-

Unless specifically precluded by national legislation or regulations, hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients. All patients should have an evaluation of the appropriateness of all their medication including herbal and dietary supplements on admission. All the medicines used by patients should be entered on the patient's medical record and confirmed by the hospital pharmacist.

Partner health organisations



No significant comments were made by Partner Health organisations.

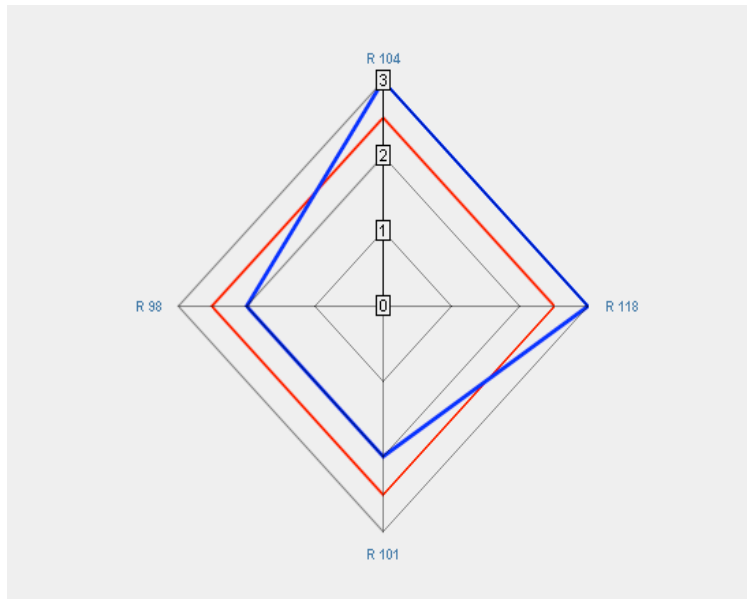
Action: an amended statement is proposed for the Delphi 2 process:-

Unless specifically precluded by national legislation or regulations, hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients. All patients should have an evaluation of the appropriateness of all their medication including herbal and dietary supplements on admission. All the medicines used by patients should be entered on the patient's medical record and confirmed by the hospital pharmacist

Aspect: Production & Compounding

3.1 Medicines not commercially available for special groups of patients that require compounding or production should be prepared by a hospital pharmacy. (Statement 15).

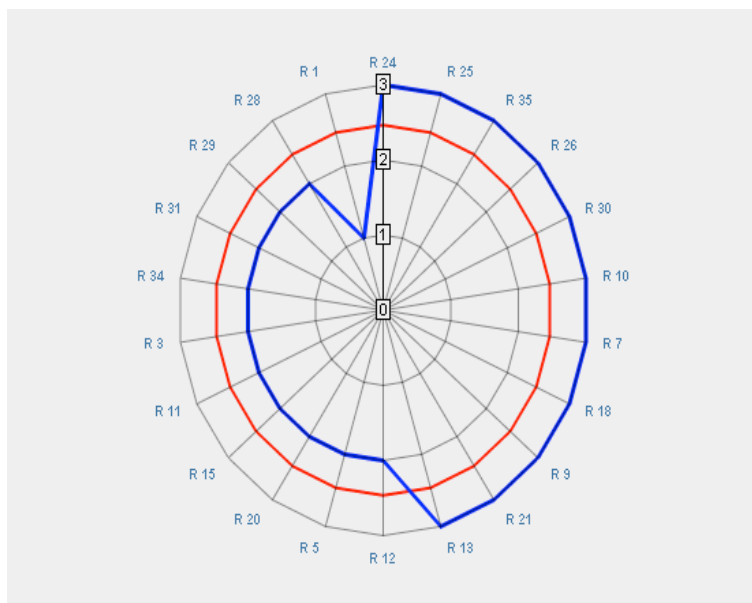
Patient groups



Average score: 2.5

No significant comments were made by Patient Groups.

EAHP Members



Average score: 2.45

Only pharmacists have appropriate training and education for this activities

What about in the case of small hospital pharmacies that do not have adequate conditions for the preparation of drugs? I think that outsourcing of services for such cases should also be defined.

It should be also stated that it is imperative that the hospitals provide the necessary infrastructure for these activities. Also, reimbursement should cover technological/supplementary costs, like that of personal protective equipment, closed systems, LAF cabinets, etc.

Hospital pharmacies should have the facilities or arrangements (contract manufacturing) in place for the production of medicines for individual or small patient populations, when not commercially available. The Hospital Pharmacist should be aware of compounding and production practices within the hospital and should attempt to conduct this activity in the hospital pharmacy. The preparation of ready to use injectables should be possible even if the product is commercially available but not at the right concentration.

yes by pharmacy technicians or hospital pharmacists (they should at least supervise)

Medicines not commercially available for special groups of patients that require compounding or production should be prepared by a hospital pharmacy, or under the supervision of the hospital pharmacy.

Given appropriate facilities and training of the nurses as directed by law, in some countries it would be appropriate for simple compounding to take place on the ward.

If production conditions and resources for such a production exist.

provided there is no delay in the treatment of patients with 24 hour access to pharmacy but it would not be high on our investment portfolio

If there is really not an alternative that is comparable the best outcome for the patient, the hospital pharmacist should discuss this with the doctors and see if it is possible to prepare, but I can imagine that there are preparations that cannot be done by the hospital pharmacy for different reasons, such as equipment, shortage of compound products and not forget the discussion concerning the cost of a such preparation for the patient.

Medicines not commercially available for special groups of patients that require compounding or production should be prepared by a hospital pharmacy but only for patients of the hospital. In our country is not allowed the hospital pharmacies to sell medicines. If they prepare medicines for everyone who will pay? I think if the patient is discharged it would be good to consider another treatment.

We do not see the point of 'for special groups of patients' - as all medicines that need compounding or production should be prepared by a hospital pharmacy. Also we do not see why the last bit of the original sentence has been removed, so you can add this again - but maybe it goes without saying?

Medicines not commercially available that require compounding or production should be prepared by a hospital pharmacy.

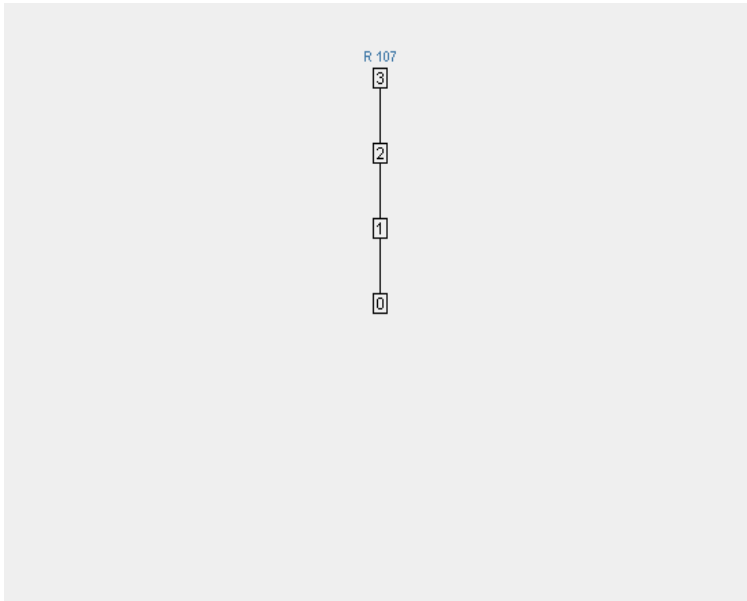
Medicines not commercially available for special groups of patients that require compounding or production should be prepared by a

hospital pharmacy, only where impossible to get commercially or where a community Pharmacy absolutely cannot prepare the preparation - if it is that hard to obtain commercially then perhaps the medication should change.

Conclusion: comments indicate that some revision is required to improve consensus. Reconstitution is the subject of later statements. Taking all comments into account the following wording is proposed for Delphi 2:-

Medicines not commercially available that require compounding or production should be prepared by a hospital pharmacy.

Partner health organisations



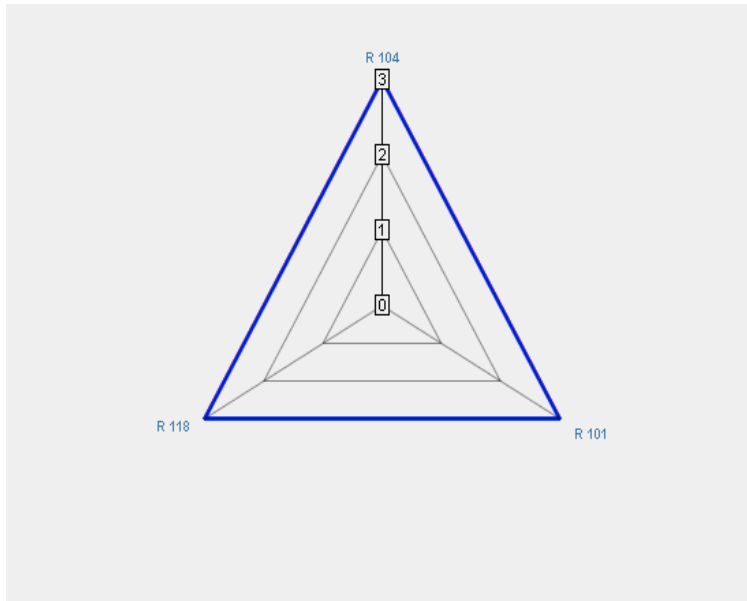
No significant comments were received from partner health organisations.

Action: Taking all comments into account the following wording is proposed for Delphi 2:-

Medicines not commercially available that require compounding or production should be prepared by a hospital pharmacy.

3.2 Hospital pharmacists should appropriately develop pharmacy-managed injectables using aseptic technique. (Statement 16).

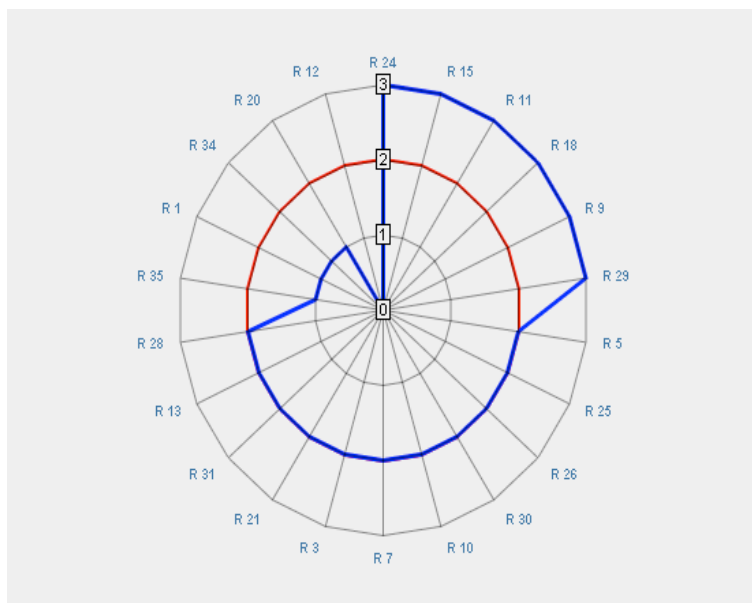
Patient groups



Average score: 3

No significant comments were received from patient groups.

EAHP Members



Average score: 2.0

The following comments were received:-

"Again pharmacists' "shortages" and low salaries is a problem"

"Definition of pharmacy-managed injectables?"

"I totally agree"

"replace by: 'Hospital pharmacists should develop a risk based concept regarding the constitution/preparation of injectables using aseptic technique.' "

"The pharmaceutical industry should reinforce their efforts to manufacture products "ready-to-administer" with fixed doses. The hospital pharmacists should prepare individual injectable medicines for patients (personalised medicine)."

"In hospital pharmacist explanation text I would add argument why hospital pharmacists should make a register of preparations that are made on the ward."

"Statement should be rewritten according to the explanation texts that states that each hospital should have sterile compounding facilities according to GMP-standards, to develop and produce i.e. prefilled syringes"

"but the concern is less contamination as there should be procedures for immediate administration of ward prepared items but more about incorrect preparation again this should be targeted at high risk medicines"

"In our everyday practice, there is an ongoing debate between physicians and pharmacists on the definitions of drug preparation and compounding. Does a simple reconstitution count as drug preparation, or is it only a part of the administering process? What about the mixing of small volume injections? Where is the division between the two categories? Unambiguous definitions would be much needed."

"Hospital pharmacists should appropriately develop pharmacy-managed injectables according to best practices"

"in Europe is there a HP that are not using aseptic technique??"

*"This sentence has changed meaning after it was changed - so this is what we think is correct: **Hospital pharmacists should appropriately develop pharmacy-manufactured injectables using aseptic technique where no commercially manufactured product is available.**"*

"in times of budget constraints there may also be reasons for dealing with products that are commercially available, this doesn't mean a loss of quality if adequately prepared in a hospital pharmacy, but could save money."

"Hospital pharmacists should appropriately develop pharmacy-managed injectables using aseptic technique - only where it is not feasible, cost effective or hazardous to have them reconstituted on a ward."

"In the Information, the statement also mentions ...where no commercially manufactured product is available"

“AND I would say, if there is no other appropriate, effective alternative therapy for the patient. Hospital pharmacies and especially the little ones cannot replace companies with a whole GMP infrastructure”

“pharmacy-managed injectables - what does this mean?”

*“Suggestion for rewording: **Hospital pharmacists should appropriately ensure that aseptic technique is applied for parenteral preparations prepared and supplied by the pharmacy”***

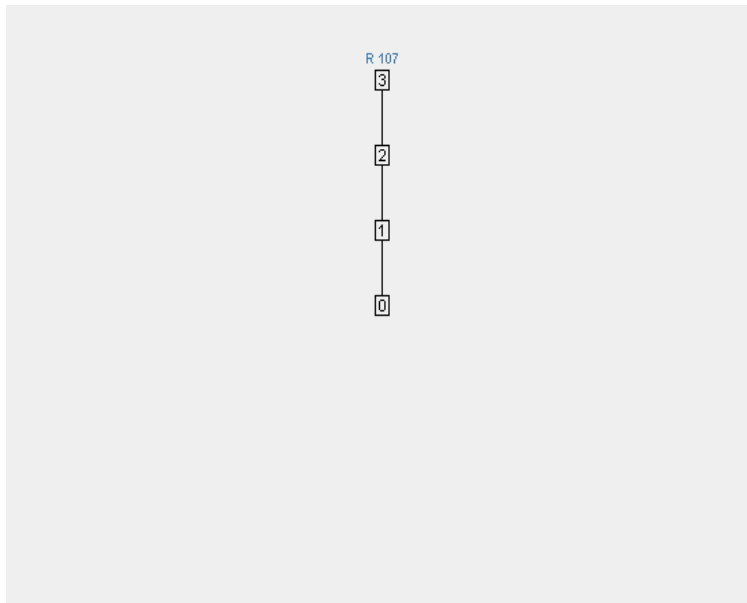
“Injections prepared and supplied by the pharmacy?”

“I strongly disagree. Hospitals pharmacists have not the necessary training in our country.”

Conclusion: comments indicate that clarification and rephrasing of this statement is required. Reconstitution is the topic of the next statement (statement 17). The issue of commercially available alternatives is covered in a later statement (statement 20). The following rewording is suggested for Delphi 2:-

Hospital pharmacists should ensure that appropriate techniques and Good Manufacturing Practice are applied in the manufacture and preparation of parenteral and other products supplied by the pharmacy.

Partner health organisations



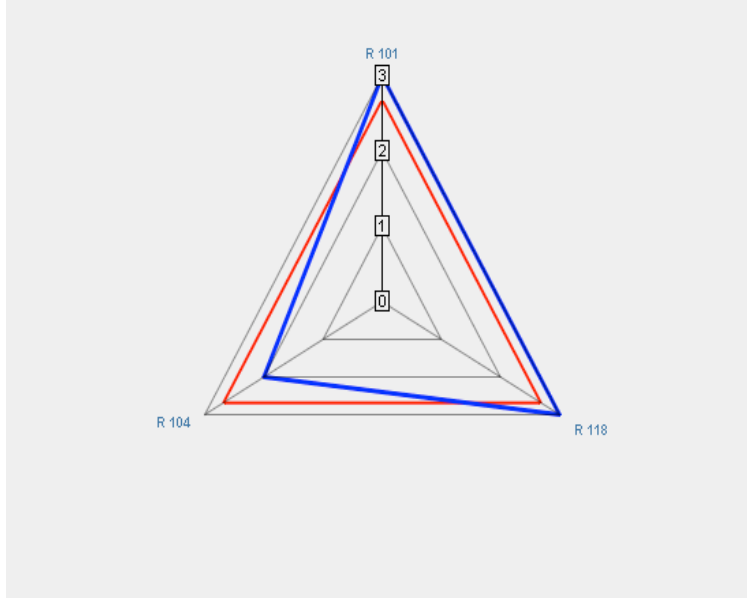
No significant comments were received from partner health organisations.

Action: The following rewording is suggested for Delphi 2:-

Hospital pharmacists should ensure that appropriate techniques and Good Manufacturing Practice are applied in the manufacture and preparation of parenteral and other products supplied by the pharmacy.

3.3 When reconstitution takes place in the ward, a hospital pharmacist should approve written procedures and ensure that the staff involved in reconstitution is appropriately trained. (Statement 17).

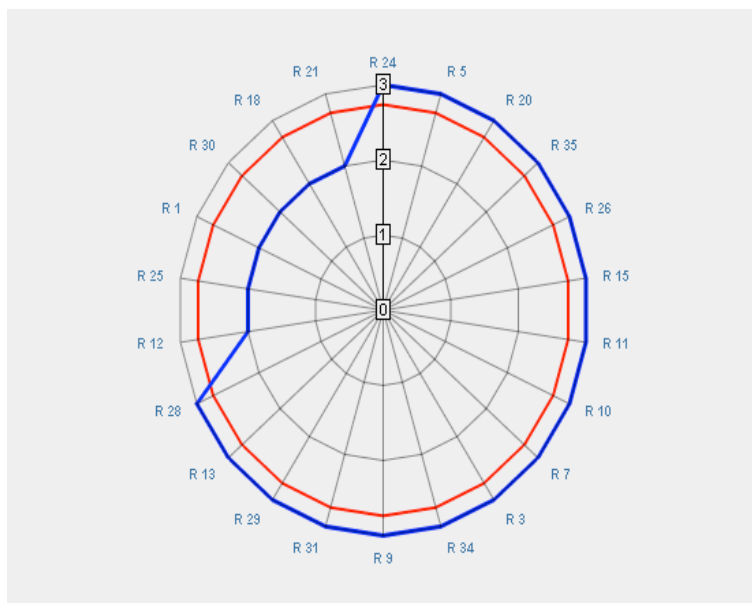
Patient groups



Average score: 2.67

No significant comments were received from patient groups.

EAHP Members



Average score: 2.73

The following comments were received:-

"Hospital pharmacists should be involved, but they should not be responsible!"

"What responsibility do you think this statement is giving to pharmacists: The training of staff? The accurate reconstitution of medicines on the ward? The accuracy of the written procedures? Which of these do you not think pharmacists should be responsible for?"

"ok - staff should in my opinion be a nurse or a pharmacy technician"

"Hospital pharmacist may even supervise written procedures implementation via pharmaceutical technicians."

"The pharmacist has to make regular audits."

"This topic is covered in the HPMM model mentioned earlier"

"but would invest pharmacist time on the clinical use not preparation and training others in preparation. May be a role for pharmacy technicians?"

"I agree - Good training to ensure quality of our pharmaceuticals activities"

"yes but I am not really sure it this the responsibility of the pharmacy to train on reconstitution (even if they can help for training) because of human resources constraints"

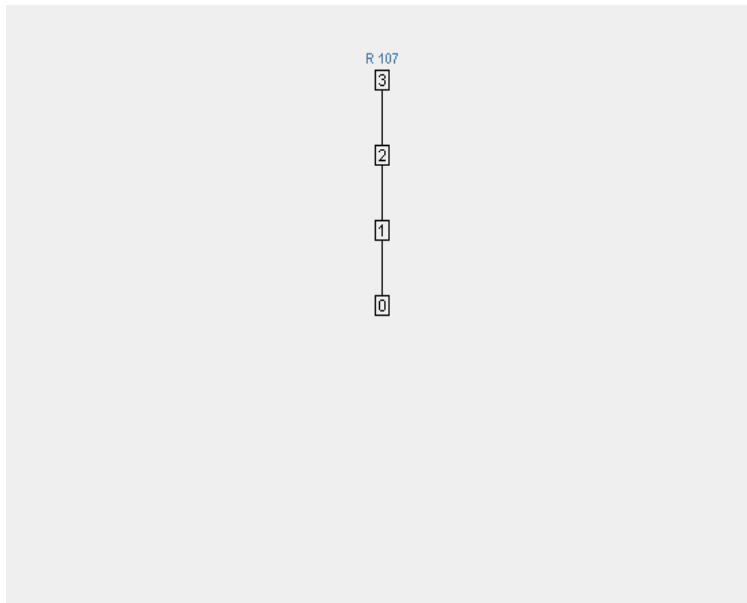
"I feel this is a role that Pharmacists could train nursing staff so that ultimately, while Pharmacists write the procedures, or direct the nurse to follow the procedure in the SmPC, the nursing staff could be trained in aseptic technique and train other staff. I feel a Pharmacist could be better employed elsewhere with the time saved."

"The main problem is lack of pharmacists and available appropriate training"

Conclusion: there is good consensus on this statement and the comments do not suggest any significant revisions. A minor wording change is proposed:-

When reconstitution takes place in the ward, a hospital pharmacist should approve written procedures and ensure that the staff involved in reconstitution are appropriately trained.

Partner health organisations



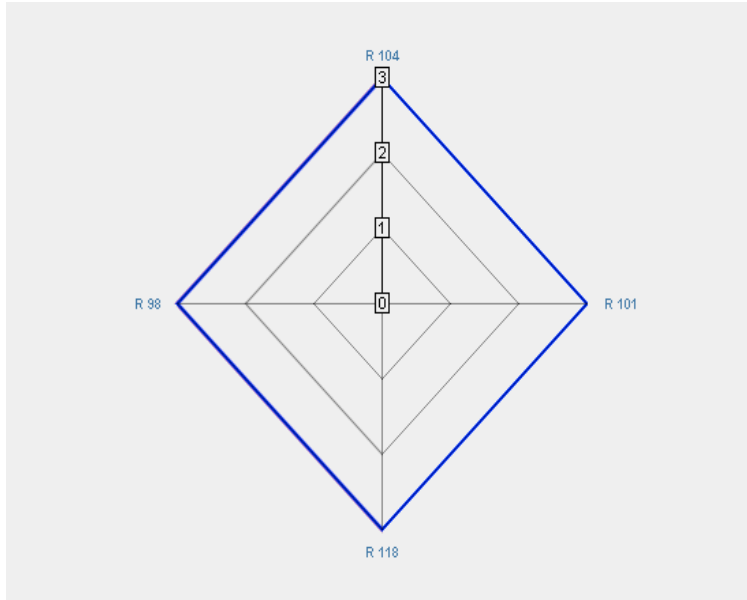
No significant comments were received from partner health organisations.

Action: a minor wording change is proposed for Delphi 2:-

When reconstitution takes place in the ward, a hospital pharmacist should approve written procedures and ensure that the staff involved in reconstitution are appropriately trained.

3.4 Hazardous medicines including cytotoxics, radiopharmaceuticals and gene therapy should be prepared under appropriate conditions that minimise the risk of contaminating the product and exposing hospital personnel and patients to harm. (Statement 18).

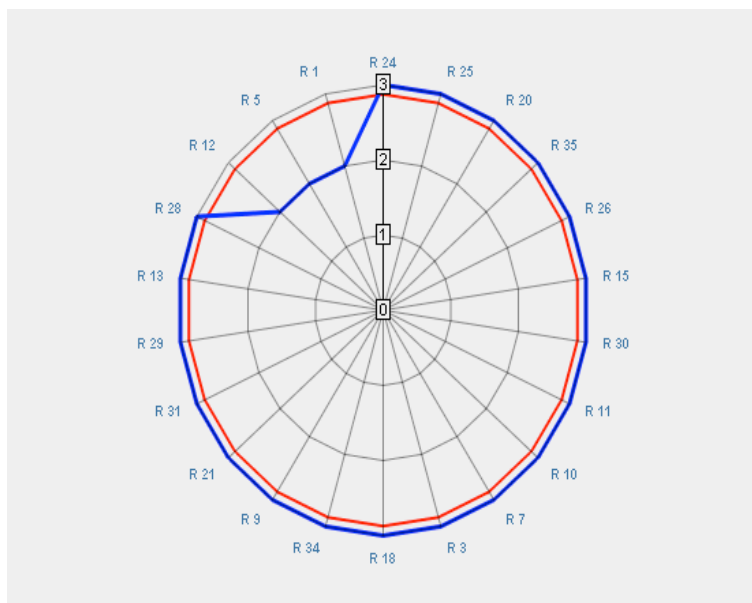
Patient groups



Average score: 3.0

No significant comments were received from patient groups.

EAHP Members



Average score: 2.86

The following comments were received:-

"The situation for hazardous medicines in our country is very very bad"

"in the controlled environment and designated aseptic units"

"This is an evidence - Preparation by the hospital Pharmacy to minimise the risk of exposing hospital personnel is an evidence but this will be optimal if we inform the hospital personnel (such nurses don't know what are those hazardous medicines and how to minimise risk during manipulation/administration."

"Preparing of these medicines under appropriate conditions also means safer environment for the patients."

"This is one of the most important statements. It should also be added though that each of these activities need their own dedicated units in order to prevent cross-contamination.2"

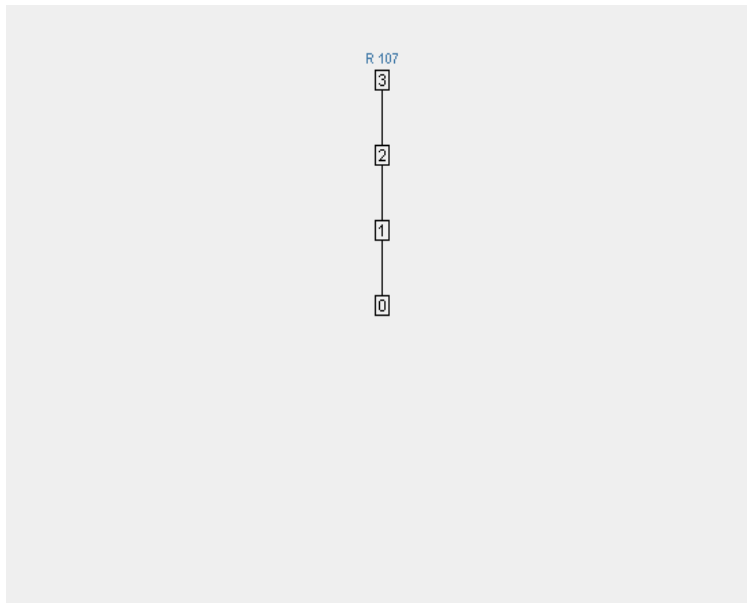
"Should gene therapy be gene therapies?"

"Hazardous medicines including cytotoxics, radiopharmaceuticals and gene therapy should be prepared under designated aseptic units that minimise the risk of contaminating the product and exposing hospital personnel and patients to harm."

Conclusion: there is excellent consensus on this statement as it stands. A minor wording change only is required.

Hazardous medicines including cytotoxics, radiopharmaceuticals and gene therapies should be prepared in appropriate conditions that minimise the risk of contaminating the product and exposing hospital personnel and patients to harm.

Partner health organisations



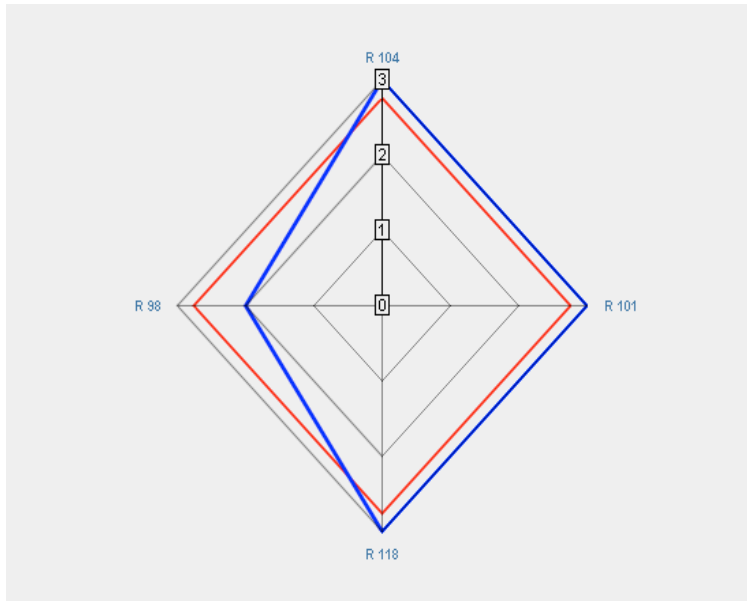
No significant comments were received from partner health organisations.

Action: the following revision is proposed for Delphi 2:-

Hazardous medicines including cytotoxics, radiopharmaceuticals and gene therapies should be prepared in appropriate conditions that minimise the risk of contaminating the product and exposing hospital personnel and patients to harm.

3.5 Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards. (Statement 19).

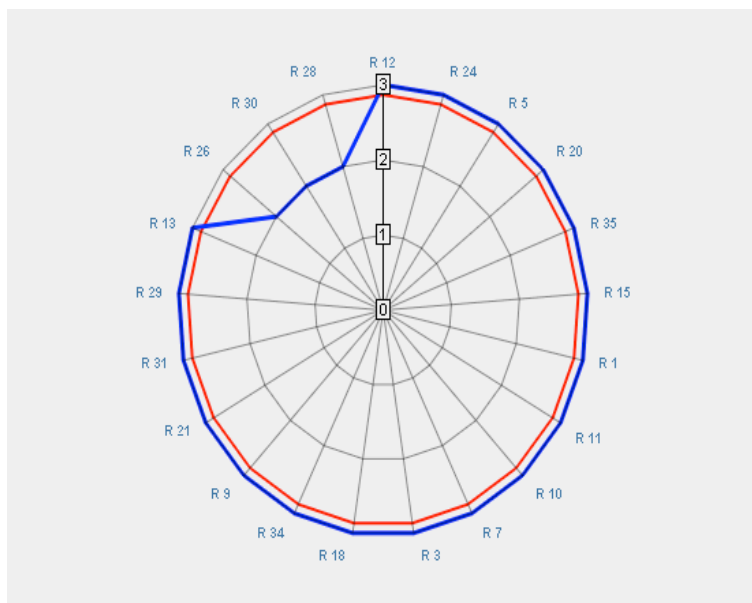
Patient groups



Average score: 2.75

No significant comments were received from patient groups.

EAHP Members



Average score: 2.86

The following comments were received:-

"Strongly agree with the statement, but not with the explanation."

"There must be the possibility to use material, which is not normally provided to be used in medicinal products (but we use it for allergy testing!)."

"The risk assessment considers the type of preparation, the amount prepared annually, the risk of the API, the preparation process and the supply; and that is sufficient."

"Of course, the products that we use to make a preparation or that we use for compounding must be completely safe and we need a proof of their quality."

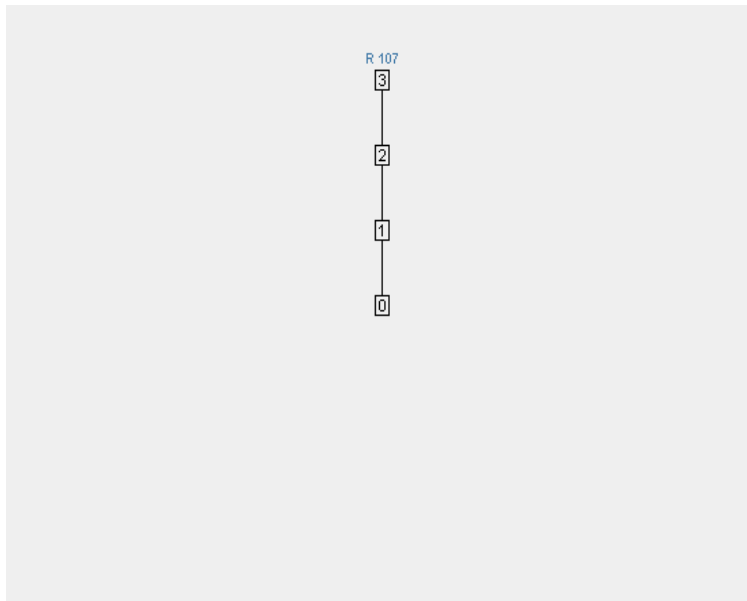
2What about the final product control/analysis?"

"I don't see why the last bit has been removed? Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with national and/or international quality standards."

Conclusion: there is excellent consensus with this statement and comments do not indicate a need for rewording. It is proposed that this statement proceed to Delphi 2 unchanged:-

Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards.

Partner health organisations



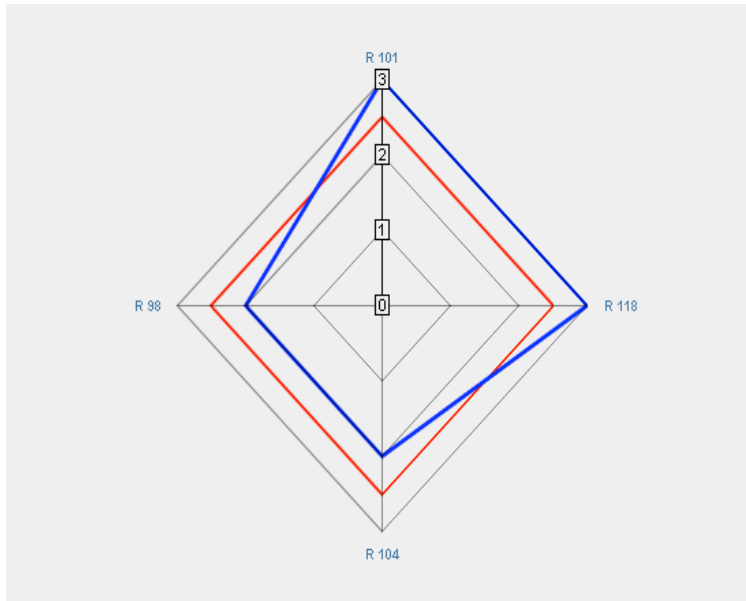
No significant comments were received from partner health organisations.

Action: this statement proceed to Delphi 2 unchanged:-

Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards.

3.6 Before preparation the pharmacist should verify whether preparations are of added value due to medical, pharmaceutical or personal reasons, needed by a specific patient or by specific population groups with particular needs. The hospital pharmacist should be able to refuse a request for a pharmacy preparation if there is a suitable pharmaceutical equivalent. Essential information about the product, based on the product dossier should be made available to patients and other healthcare professionals. (Statement 20).

Patient groups

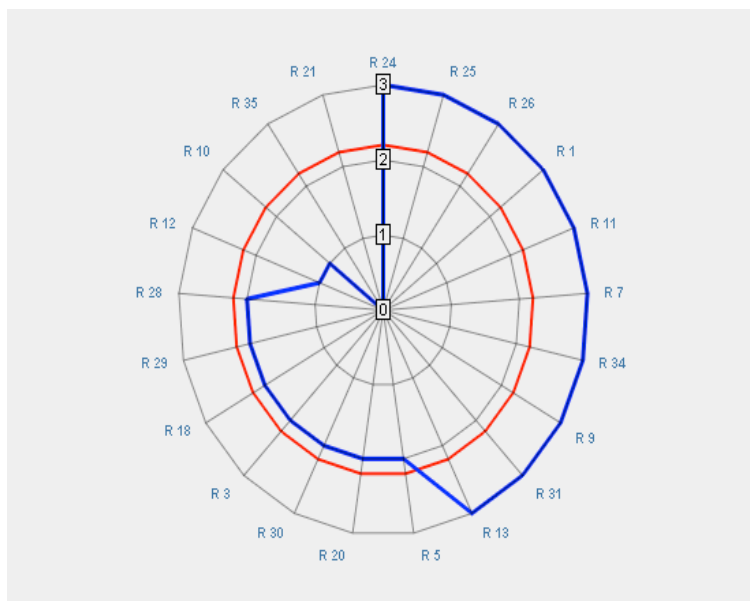


Average score: 2.5

The following comment was received from patient groups:-

"agree, however in this case, a dialogue between doctor/nurse , pharmacist and patient would be beneficial"

EAHP Members



Average score: 2.19

The following comments were received:-

"Hospital pharmacist should be able to perform Health Technology Assessment (HTA) procedures in order to verify whether preparations are of added value due to medical, pharmaceutical or personal reasons."

"both doctors and pharmacist should assess of the added value of a pharmacy preparation, especially if there is a gap in the market."

"The product dossier is not regarded as reasonable in Switzerland and is not mandatory - and should therefore not be mentioned."

"Before preparation the pharmacist should verify whether preparations are appropriate due to pharmaceutical or patient specific clinical reasons, or needed by specific population groups with particular (clinical) needs. The hospital pharmacist should be able to consult with the prescriber about a the specific pharmacy preparation, especially if there is a suitable pharmaceutical equivalent."

"not sure about this statement - maybe exclude (Essential information about the product, based on the product dossier should be made available to patients and other healthcare professionals.)"

"Can you suggest how the statement could be re-worded to reflect the specific issues in a more concise way? You have commented that the statement is very long and complicated. Are there too many issues included in the single statement and could anything be removed or be made a statement on its own?"

"but too many statements on same topic can they not be condensed? Also need to consider outsourcing to commercial specials manufacturers"

"2 words have been removed from the original sentence and that totally changes the meaning - they should be re-inserted."

"Before preparation the pharmacist should verify whether preparations are of added value due to medical, pharmaceutical or personal reasons, needed by a specific patient or by specific population groups with particular needs. The hospital pharmacist should be able to refuse a request for a pharmacy preparation if there is a suitable commercially available pharmaceutical equivalent. Essential information about the product, based on the product dossier should be made available to patients and other healthcare professionals"

"I think the physician must decide that."

"Please could you explain why you think the physician must decide upon the appropriateness of a preparation? What would be a reasonable compromise in the statement wording to reflect your views?"

"The pharmacist should verify.....but why to refuse a request for a preparation if there's a suitable equivalent? We have to use the QA system."

"My suggestion:the HP should consult the request for a preparation and the specific needs of the patient with the prescriber if there's a suitable pharmaceutical equivalent....."

"We have to be honest, preparations are also done for economic reasons in many many countries, with no minor quality. We should not go down on the knees before pharmaceutical industry. To me it is not necessary to make the possibility of refusal that explicit, it is obvious and law that we have to refuse everything that is not clear and we have doubts about for any reasons. This would also make the statement more concise".

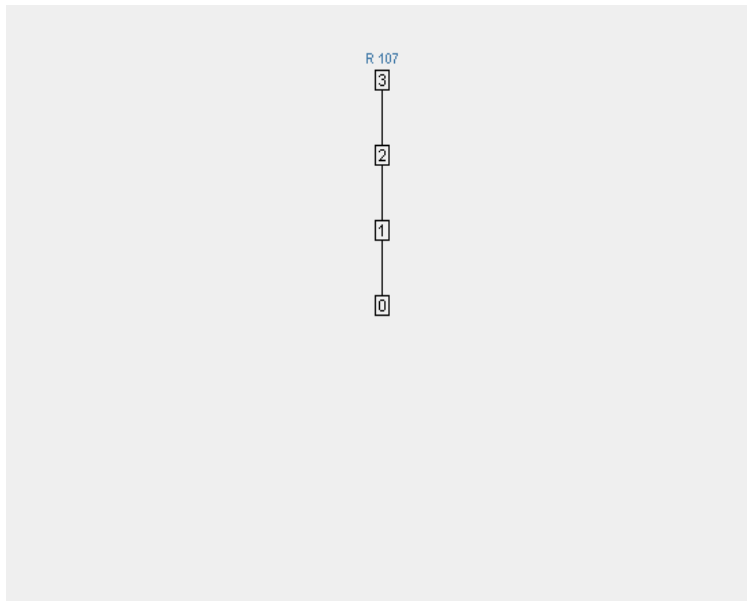
"A product dossier could be one way of delivering information, information in the formulary about pharmacy own preparations could be another. There may be different ways of information. We should not narrow ourselves here."

"This should be a team decision. Also, the exact meaning of 'added value' is not very clear in this context."

Conclusion: the comments suggest some rewording is required, particularly in the direction of a dialogue with the prescriber rather than a refusal. The following wording is proposed for Delphi 2:-

Before pharmacy manufacture or preparation of a medicine, the hospital pharmacist should ascertain whether there is a suitable commercially available pharmaceutical equivalent, and if necessary discuss with the health care team whether pharmacy preparation is appropriate for a specific patient or group of patients.

Partner health organisations



The following comments were received from partner health organisations:-

"In the statement / information text '... is a complex one and doctors and pharmacists should....' "

"To consider the input of nurses based on common understanding of risks."

"Example of personal experience in mental health. Patient diagnosed with schizophrenia was treated with Leponex'specialite' but later on to similar product Clozapine. But during process 2 clients (with lower physical health status and unriable communication ability) suffered severe bowl obstruction with once a critical intestinal perforation. After period of having discussion and going back to Leponex, both patients showed less bowel problems and nurses monitor closely side effects. It proved that at ward -with nurses input- prescribing policy can contribute to safe medicine use."

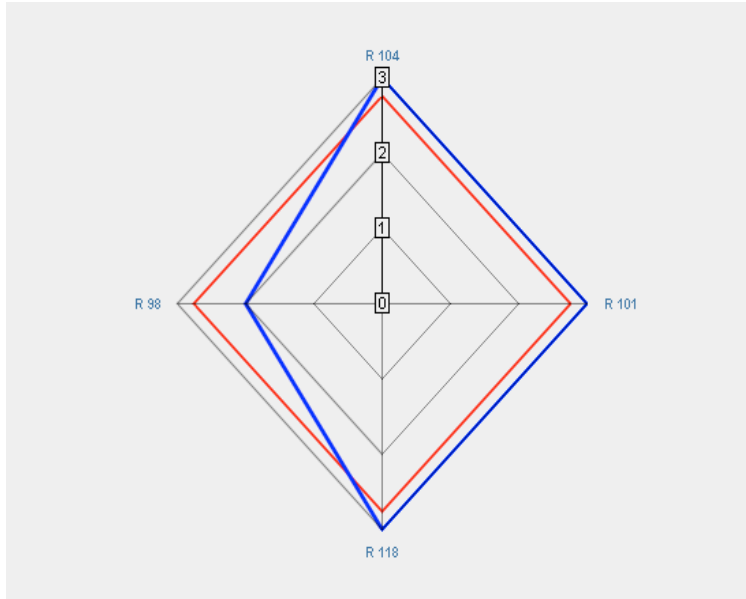
"The process was closely discussed with nurses, share responsibility and accountability in decisions. So may add '... is a complex one and doctors -nurses- and pharmacists should....' "

Action: the following wording is proposed for Delphi 2:-

Before pharmacy manufacture or preparation of a medicine, the hospital pharmacist should ascertain whether there is a suitable commercially available pharmaceutical equivalent, and if necessary discuss with the health care team whether pharmacy preparation is appropriate for a specific patient or group of patients.

3.7 When making a pharmacy preparation, the pharmacist should always undertake an appropriate risk assessment in order to determine the level of the quality system which should be applied to the preparation of the medicinal product. Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured through the whole process from production to administration. (Statement 21).

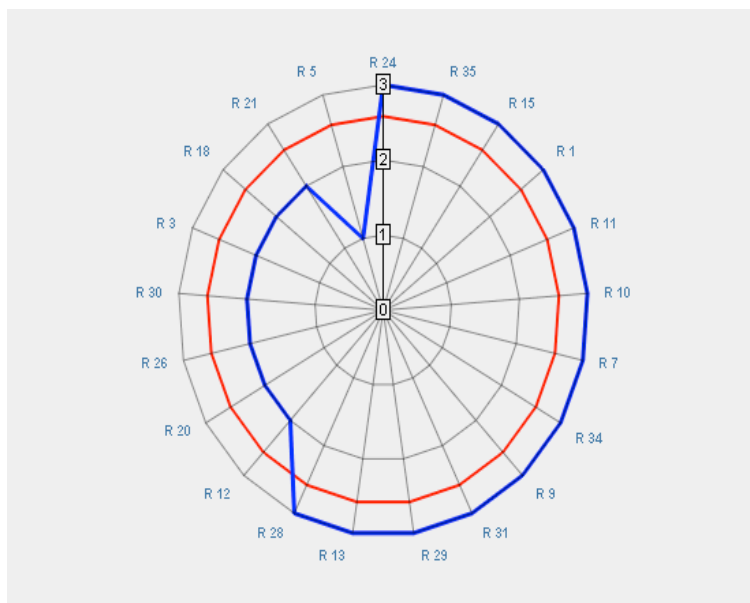
Patient groups



Average score: 2.75

No significant comments were received from patient groups.

EAHP Members



Average score: 2.57

The following comments were received:-

"A preparation must always be made as it would be for yourself. Thus, pharmacy preparations must be as safe as industrial pharmaceutical preparations"

"well ... 'when' making a preparation is too late ... could it be 'before' pharmacy preparations are made"

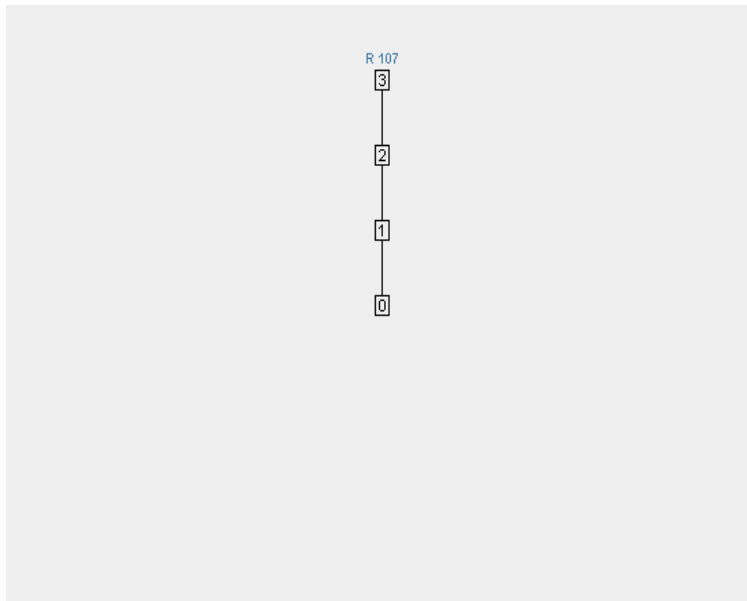
"but too many statements on same topic can they not be condensed? "

"disagree with the statement - strongly agree with the explanation. In Switzerland, the level of the quality system for pharmacy preparations is given in the pharmacopoeia, and therefore it is independent of the risk assessment!. The pharmacist cannot decide to use a less rigid quality system."

Conclusion: despite only good consensus (as opposed to very good or excellent), the comments from Delphi 1 do not indicate an approach to improving this statement other than a minor wording change. It is therefore proposed that the statement goes forward as below for further consideration in Delphi 2:-

Before making a pharmacy preparation, the pharmacist should always undertake an appropriate risk assessment in order to determine the level of the quality system which should be applied to the preparation of the medicinal product. Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured throughout the process from production to administration.

Partner health organisations



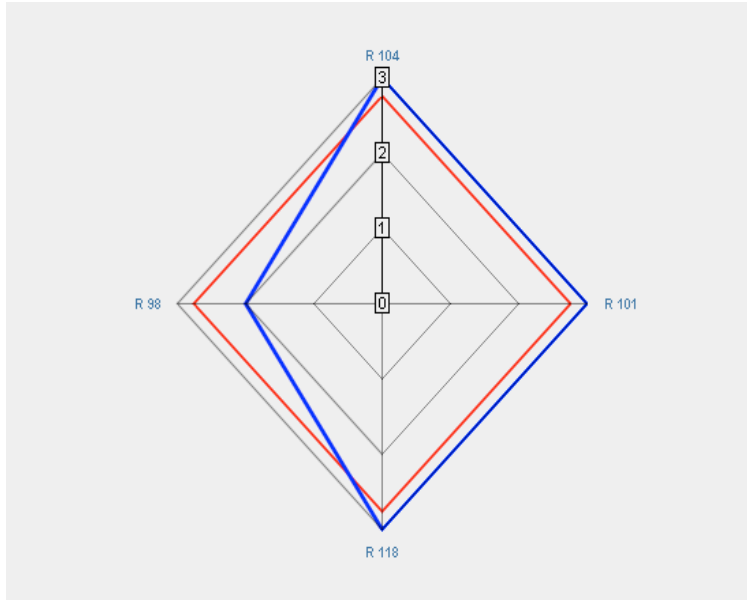
No significant comments were received from partner health organisations.

Action: it is proposed that the statement goes forward with minor wording changes for further consideration in Delphi 2:-

Before making a pharmacy preparation, the pharmacist should always undertake an appropriate risk assessment in order to determine the level of the quality system which should be applied to the preparation of the medicinal product. Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured throughout the process from production to administration.

3.8 An appropriate system for quality control and quality assurance should in place, ensuring traceability for pharmacy produced and compounded medicines, in the interest of patient safety. (Statement 22).

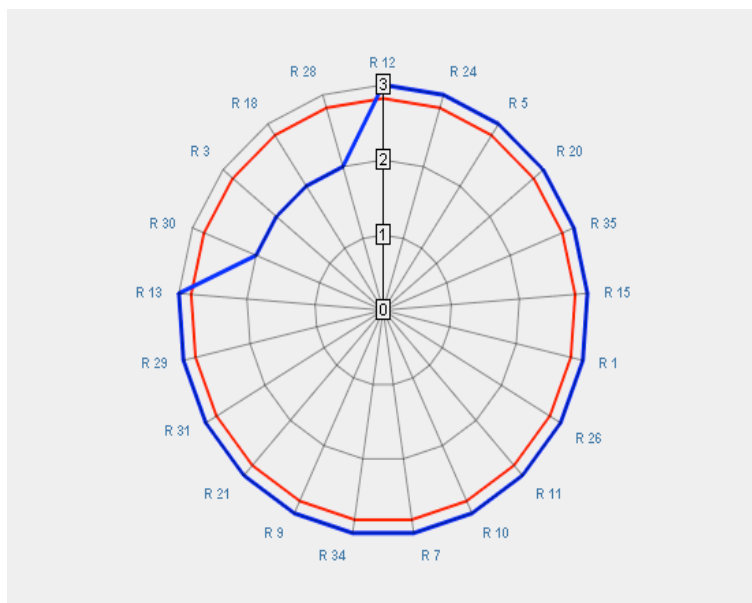
Patient groups



Average score: 2.75

No significant comments were received from patient groups.

EAHP Members



Average score: 2.81

The following comments were received:-

"Not only for patients but for pharmacists protection too"

"There should not be the need for an electronic database. A paper-based documentation is sufficient."

"This system should be linked to public pharmacies via seamless care system."

"ensuring traceability is a good quality process"

"Strongly agree. an appropriate tracking system should be implemented, similar to the licensed drugs"

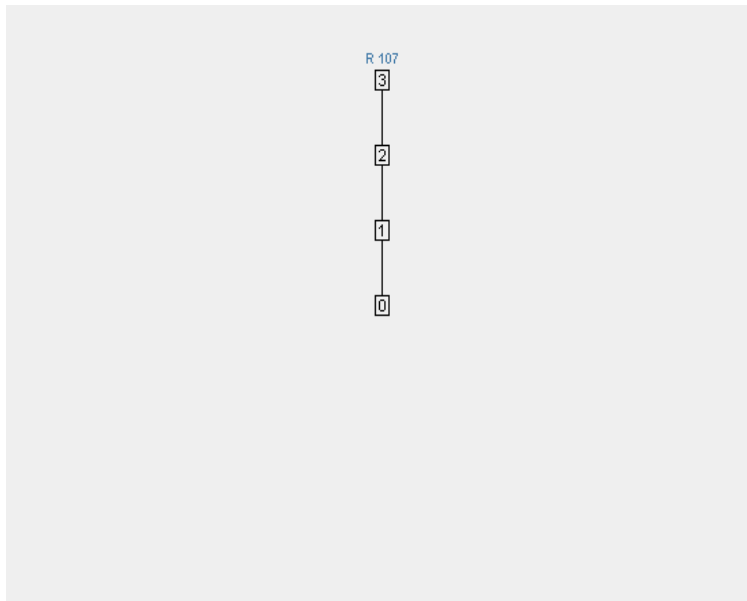
"On hindsight should there not be one overriding statement per category that states why this domain requires the input of and derives value from the pharmacist then you could have sub -statements and it may be more succinct? E.g. Clinical, production, safety etc"

*"A suggestion to make this stronger and better plus change of and 'and' to 'or' as a specific product will not be both produced and compounded. An appropriate system for quality control and quality assurance should in place, ensuring **documentation and traceability for pharmacy produced or compounded medicines, in the interest of patient safety.**"*

Conclusion: after carefully considering all comments, excellent consensus is already achieved and a minor wording change only is required for Delphi 2. The proposed statement is:-

In the interest of patient safety, an appropriate system for quality control and quality assurance should be in place, ensuring traceability for pharmacy produced and compounded medicines.

Partner health organisations



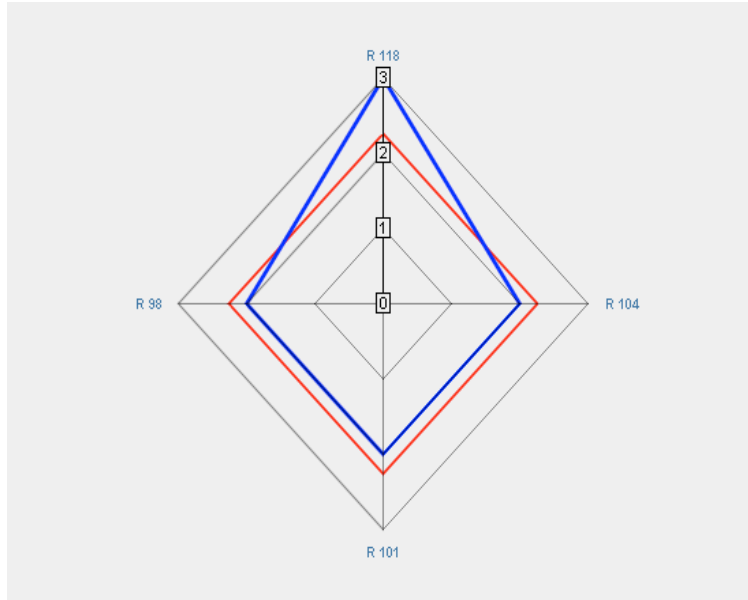
No significant comments were received from partner health organisations.

Action: a minor wording change only is required for Delphi 2. The proposed statement is:-

In the interest of patient safety, an appropriate system for quality control and quality assurance should be in place, ensuring traceability for pharmacy produced and compounded medicines.

3.9 Hospital pharmacists should be involved in all patient care areas to prospectively influence collaborative therapeutic decision-making and should have access to the patients' health record. (Statement 23).

Patient groups



Average score: 2.25

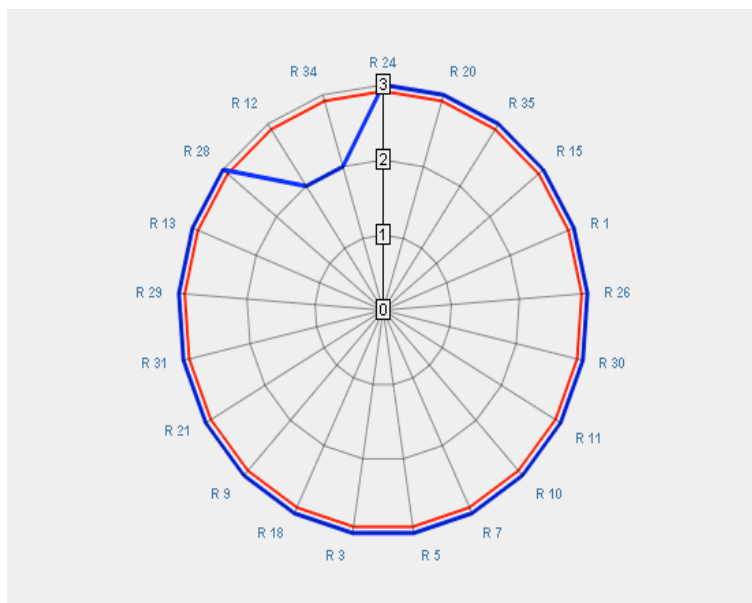
The following comments were received:-

“access to health records would be beneficial in understanding the 'medicine history' of the patient. however this debate should be discussed with doctors and patients”

“some doubts on privacy rules”

“Agree they should have access to parts of the EHR but don't think that HPs must be involved in all patient care areas.”

EAHP Members



Average score: 2.9

The following comments were received:-

"Especially in ICU."

"Yes - maybe instead of saying "all" - all appropriate or all major"

"Agreed"

"Comment: Why is this statement under the heading "Production & Compounding"?"

*"A word should be added: Hospital pharmacists should be involved in all patient care areas to prospectively influence collaborative and **multidisciplinary** therapeutic decision-making."*

"Not sure on category but increasingly pharmacists will be responsible for implementing therapeutic plan including prescribing"

"Hospital pharmacists must integrate health care teams and influence decision regarding medication use, so full access to all clinical data is mandatory. to spread pharmacy clinical services must be the goal since though it isn't our most visible activity it is the one that will most contribute to the reduction of pharmacotherapeutic morbidity."

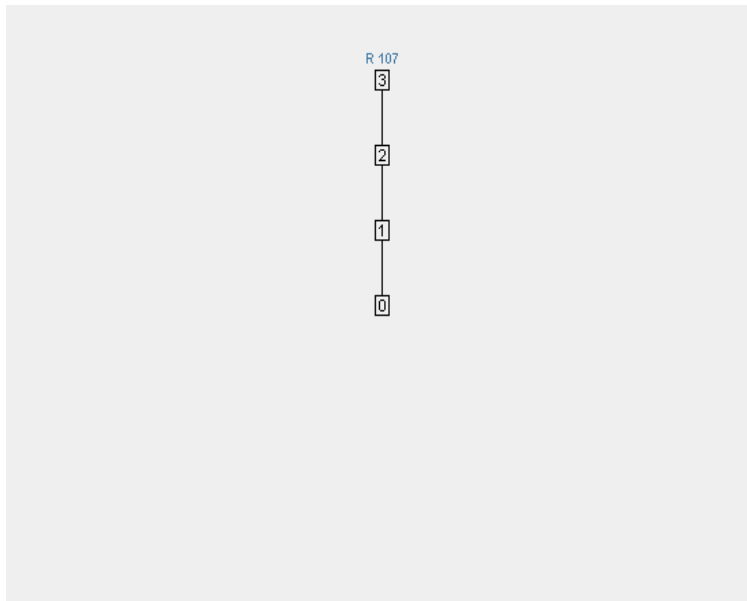
"This belongs in the Clinical Services section, not in Production and Compounding ;-)"

"hospital pharmacist need all clinical data of his patient to give the best pharmaceutical advice"

Conclusion: this is in the wrong section and should be moved to section 4, after 4.2 or 4.3. There is already excellent consensus on this statement and minor wording changes only are suggested by the comments. The statement proposed for Delphi 2 is as follows:-

Hospital pharmacists should be involved in all patient care settings to prospectively influence collaborative, multidisciplinary therapeutic decision-making; they should have access to the patients' health record.

Partner health organisations



No significant comments were received from partner health organisations.

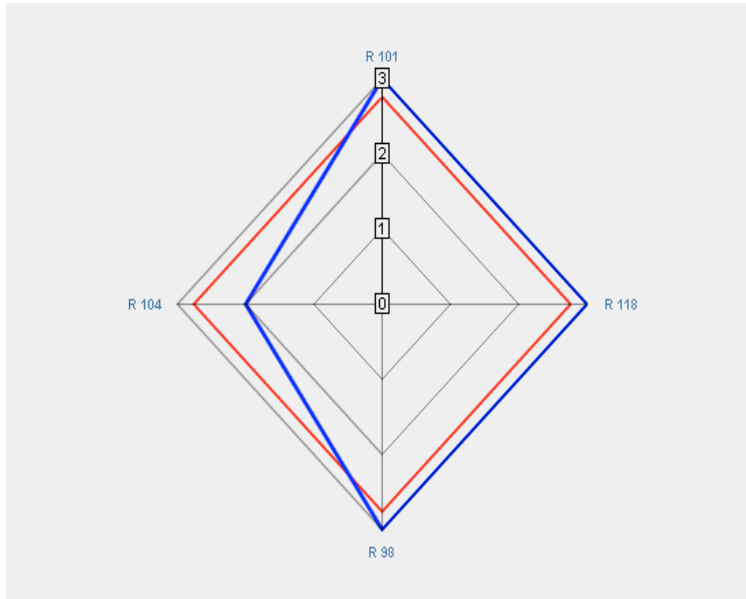
Action: **move this statement to section 4, after 4.2 or 4.3.** The statement proposed for Delphi 2 is as follows:-

Hospital pharmacists should be involved in all patient care settings to prospectively influence collaborative, multidisciplinary therapeutic decision-making; they should have access to the patients' health record.

Aspect: Clinical Services

4.1 Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients outcomes. (Statement 24).

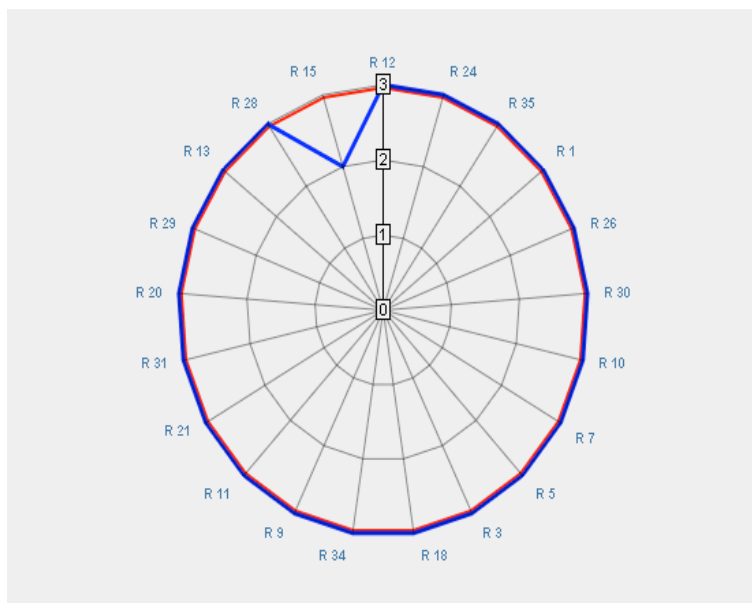
Patient groups



Average score: 2.75

No significant comments were received from patient groups.

EAHP Members



Average score: 2.95

This statement has excellent consensus already. Few comments were received.

"It makes absolutely sense to focus mainly on high risk patients as human resources are often limited."

"but it may not just be high risk medicines but the overall therapeutic management of high risk patients e.g. frail elderly or long term conditions "

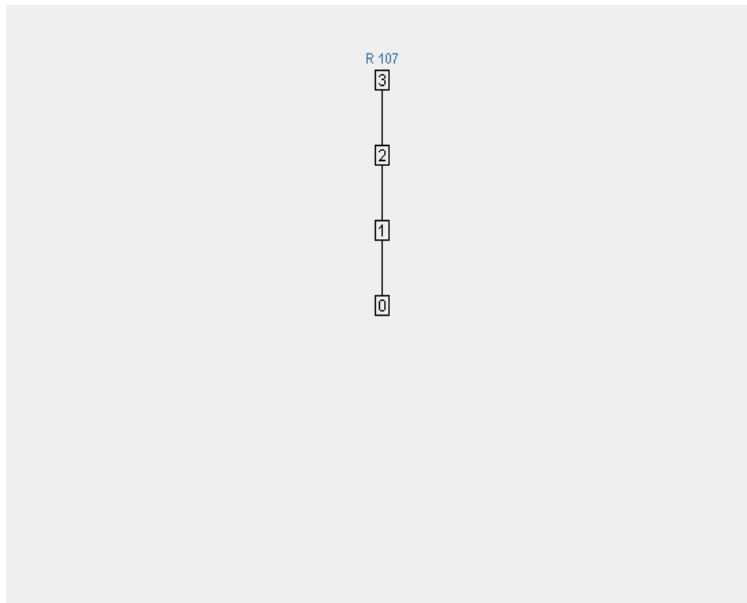
"This is our goal, but it is difficult to have all the high risk patients under control of clinical pharmacists without enough human resource and support"

"Rewording suggestion: 'Clinical pharmacy services should, in collaboration with other health care personnel, continuously develop to manage medication therapy to optimise patients outcomes.' "

Conclusion: no revision of this statement is proposed for Delphi 2.

Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients' outcomes.

Partner health organisations



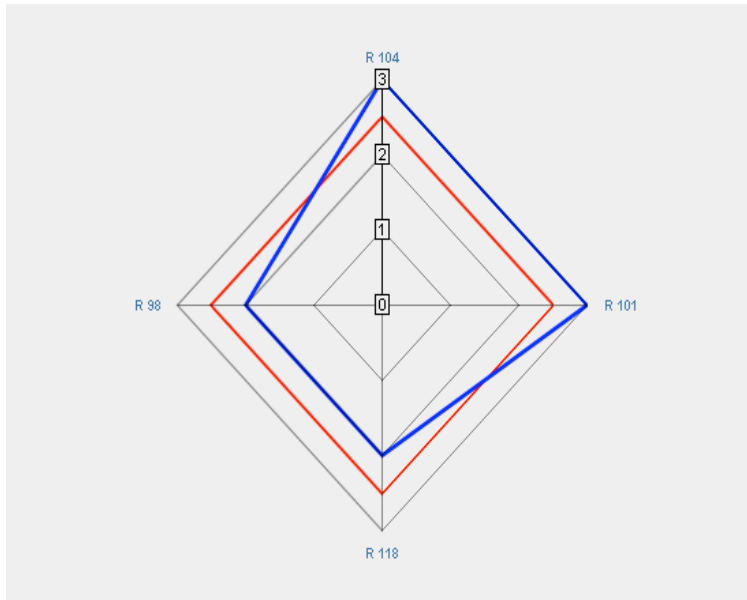
No significant comments were received from partner health organisations.

Action: no revision of this statement is proposed for Delphi 2.

Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients' outcomes.

4.2 Hospital pharmacists are an integral part of all patient care teams to assist with therapeutic decision-making and advise on clinical pharmacy and patient safety issues. This ensures that Hospital pharmacists are accessible for patients and other healthcare professionals. (Statement 25).

Patient groups



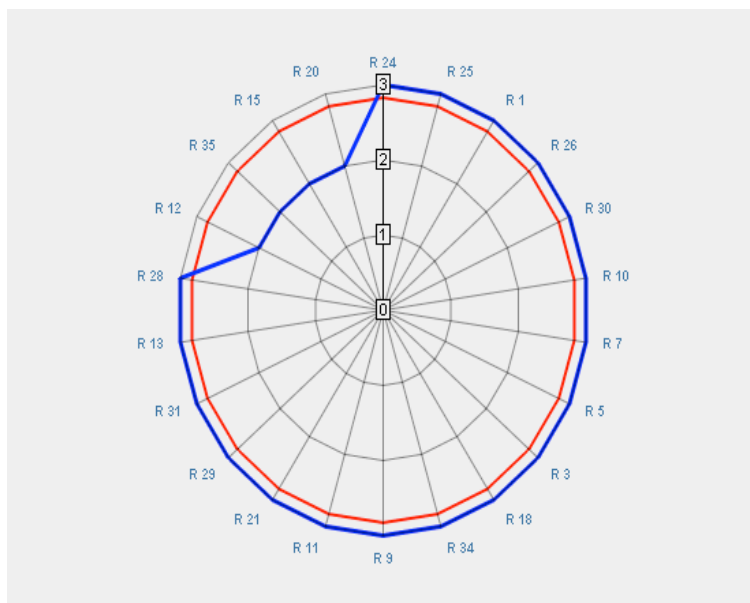
Average score: 2.5

The following comments were received from patient groups:-

Add that patients should be informed about the role of hospital pharmacists and how to contact them. Pharmacists may require training on effective communication with patients.

Yet, it does not seem that HPs are very accessible in most countries.

EAHP Members



Average score: 2.82

The following comments were received:-

"Should we talk more about medication safety than patients safety?"

"Teamwork has proven to be the easiest and most effective way of improving medicine use"

"if clinical pharmacy is ensuring the effective and appropriate use of medicines"

"with an optimal training and experience2"

"the key is to maintain sustainable clinical services and at consistent high standard. training and sustainable human resources are mandatory."

"I am not sure if people outside the pharmacy world have an idea of clinical pharmacy issues - maybe "all medication therapy related issues" would be easier to understand for non-pharmacists and other health professionals."

2Statement 4.1 and 4.2 are quite similar. Would it be possible to combine them?"

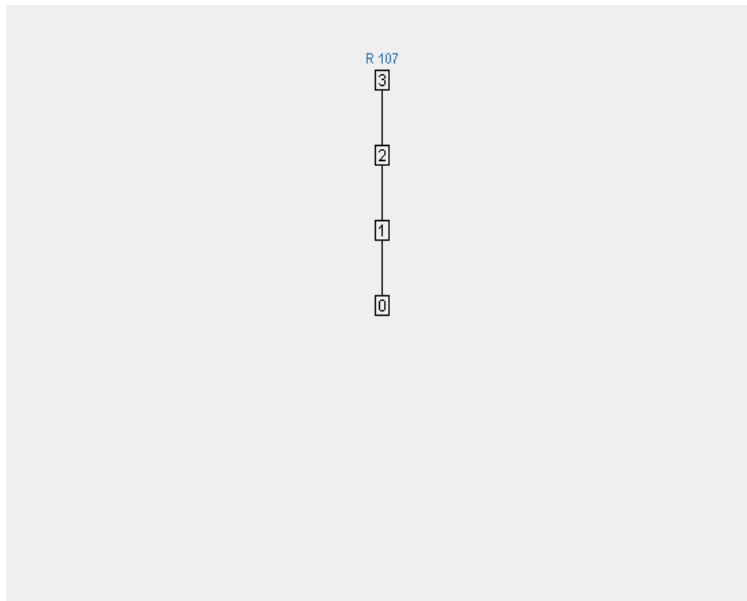
"to assist - better to say be part of the therapeutic decision making 2"

"advise - I would use a stronger word e.g. consult"

Conclusion: taking all comments into account, despite the very good consensus already, this statement can be revised for Delphi 2. The following is proposed:-

Hospital pharmacists should be an integral part of all patient care teams advising especially on therapeutics, clinical pharmacy and patient safety issues; they should play a full part in decision making in partnership with patients and other health care professionals.

Partner health organisations



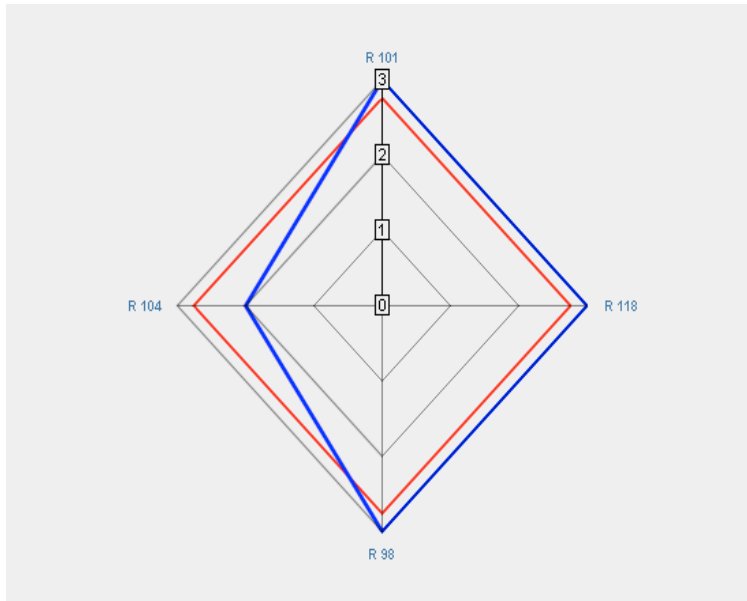
No significant comments were received from partner health organisations.

Action: this statement can be revised for Delphi 2. The following is proposed:-

Hospital pharmacists should be an integral part of all patient care teams advising especially on therapeutics, clinical pharmacy and patient safety issues; they should play a full part in decision making in partnership with patients and other health care professionals.

4.3 All prescriptions should be reviewed and validated by a hospital pharmacist prior to dispensing and administration of medication. (Statement 26).

Patient groups

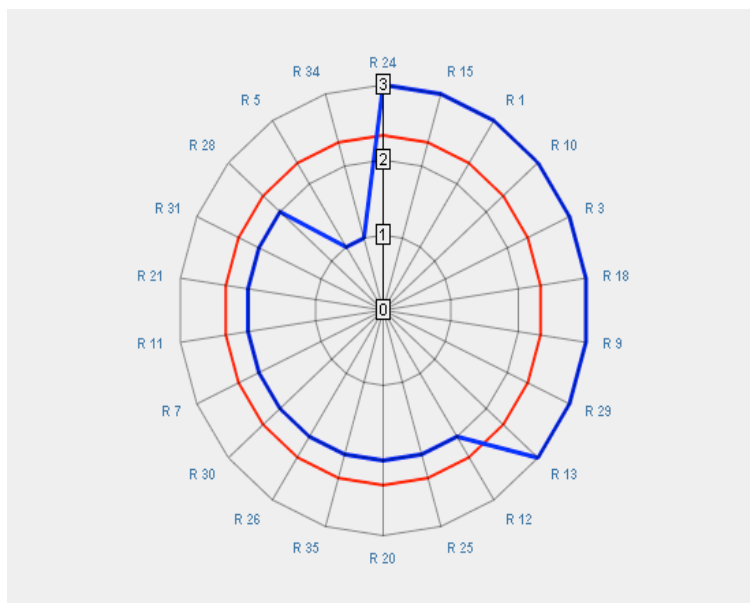


Average score:

The following comment was received:-

Partially agree- organization of the hospital may not allow such a review on a daily basis. Pharmacist should consult with physicians who are responsible for prescribing medications

EAHP Members



Average score: 2.32

The following comments were received:-

"Especially before administration on the wards. Medications on the wards are administered by nurses."

"and accept that this needs 24/7 pharmacist access"

"In my country, we do not see the prescription and we are dispensing drugs on wards."

"to systematically review and validate all prescriptions prior to dispensing and administration is a quality standard. By doing it, pharmacist will contribute in reducing risk of medication errors and to the appropriate use of medicines."

"Yes however not always possible (emergency situations)"

"yes preferably through an electronic system and using medicines reconciliation procedure"

"Electronic systems are good for recording and preventing actions such as dispensing/administration without authorisation but it requires the patient interface of processes such as medicines reconciliation to ensure you are correctly validating"

"A lot cheaper than unit dose systems for example?"

"all non-emergency prescriptions or in the OR - there can never be a review of all prescriptions"

"In ideal word yes, but do we have here statement or vision? I agree that hospital pharmacists should review and validate prescriptions but if we want that the statements are true in near future, we cannot talk about all patients prior dispensing/administration because the clinical pharmacy services are in many countries only developing. And do we have enough hospital pharmacists for this? I don't think so at the moment. Can we at least leave "all" away from the statement?"

"individual dispensing is not standard in all European countries, it should be the goal, but there is still a long way to go"

"Depending on type of prescription, reviewing and validation carried out by a hospital pharmacist should be more or less facilitated via information technology systems."

"A very idealistic approach indeed. I seriously doubt its ubiquitous feasibility throughout the whole EU."

"I agree with the above"

*"The sentence below is one suggestion.. Relevant patients or therapies could then be defined locally i.e. groups at risk, children, elderly or according to risk in relation to the medication. Alternatively the revision should be under the responsibility of a pharmacist **For all relevant patients and therapies** prescriptions should be reviewed and validated by a hospital pharmacist prior to dispensing and administration of medication."*

"Monitoring ALL the patients is impossible in many countries today and probably for a pretty long time. It would be much more realistic to talk about "all the patients under the supervision of the clinical pharmacists". This statement contrasts with the comment belonging to statement 24 saying that pharmacists should focus on high risk patients. In many countries clinical pharmacists are not on duty 24/7."

"The best way would be by the electronic prescription. All prescriptions...it is not possible (emergency, intensive care..) perhaps"

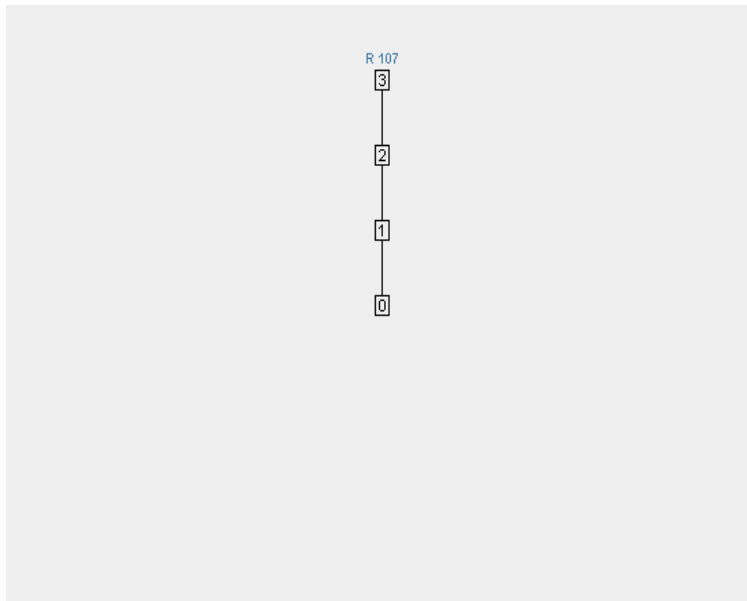
"Most of prescriptions.. this is a noble statement, but in practice, a review of all prescriptions by pharmacists is in a 700 bed hospital impossible. We calculated this; we need 7.5 full time pharmacists 8 hours a day, weekends included to make a review of all prescriptions and then we have not a validation outside those 8 hours a day."

"So, for a review, the hospital must have a CDS system to do a review electronically and for high risk patients and for high risk medications, a review can maybe be possible - If someone can explain me how he or she can manage this statement with hospital pharmacists, I would like to hear it"

Conclusion: reviewing all the comments, the introduction of some caveats will improve the consensus in Delphi 2 without diluting the important principle this statement sets out to establish. The following revision is proposed:-

Whenever the clinical situation allows, all prescriptions should be reviewed and validated as soon as possible by a hospital pharmacist; this review should preferably take place prior to the dispensing and administration of medication.

Partner health organisations



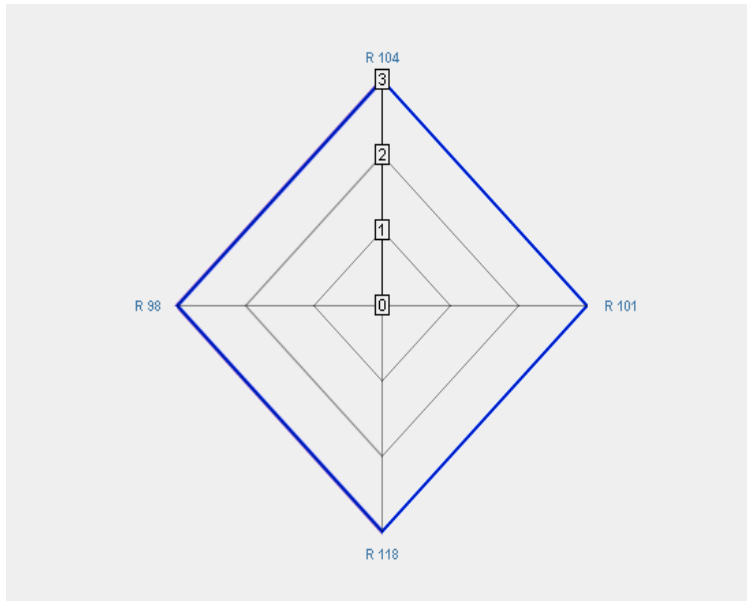
No significant comments were received from partner health organisations.

Action: the following revision is proposed for Delphi 2:-

Whenever the clinical situation allows, all prescriptions should be reviewed and validated as soon as possible by a hospital pharmacist; this review should preferably take place prior to the dispensing and administration of medication.

4.4 Pharmacists' clinical interventions should be documented in the patients' health record. (Statement 27).

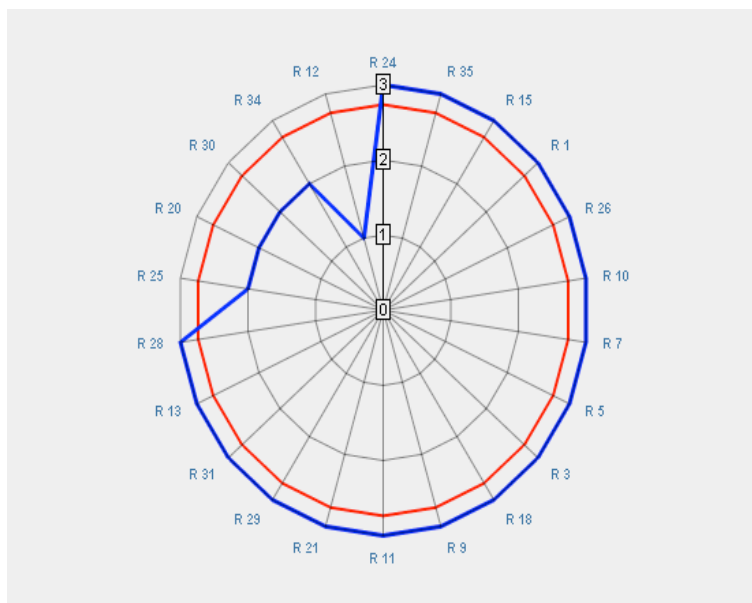
Patient groups



Average score: 3.0

No significant comments were received from patient groups.

EAHP Members



Average score: 2.73

The following comments were received:-

"This is the only manner pharmacists to evident their activity"

"Documenting clinical interventions in the patient chart is also important on a political point of view as it is a sign of pharmaceutical involvement."

"These interventions should be linked to primary care level pharmacists interventions via seamless care health records."

"Strongly agree. responsabilization and safety issues."

"yes but only the more relevant2"

"electronically is best and not just document the intervention, document everything you do for the patient also medication list, indication, dose - drug therapy problems and solution to solve them and follow up"

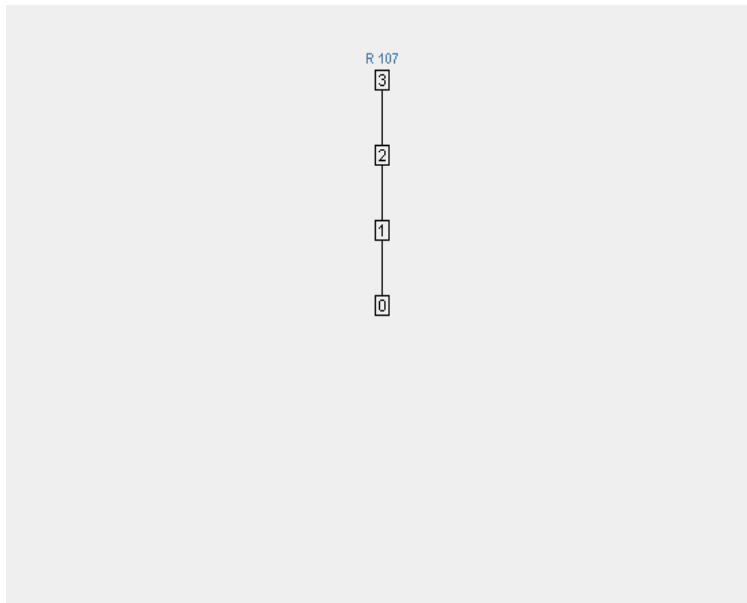
"Pharmaceutical advice must be into account in a pharmaceutical record integrated in the medical record (electronic way is the best). Not all clinical interventions but the most relevant."

"I disagree."

Conclusion: comments do not suggest any useful revisions to the statement. No changes are proposed for Delphi 2:-

Pharmacists' clinical interventions should be documented in the patients' health record

Partner health organisations



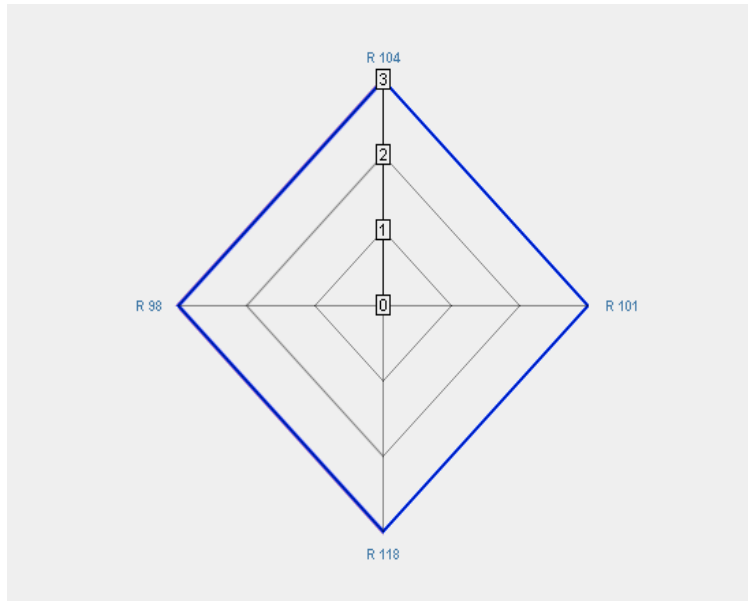
No significant comments were received from partner health organisations.

Action: No changes are proposed for Delphi 2:-

Pharmacists' clinical interventions should be documented in the patients' health record

4.5 Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings. (Statement 28).

Patient groups



Average score: 3.0

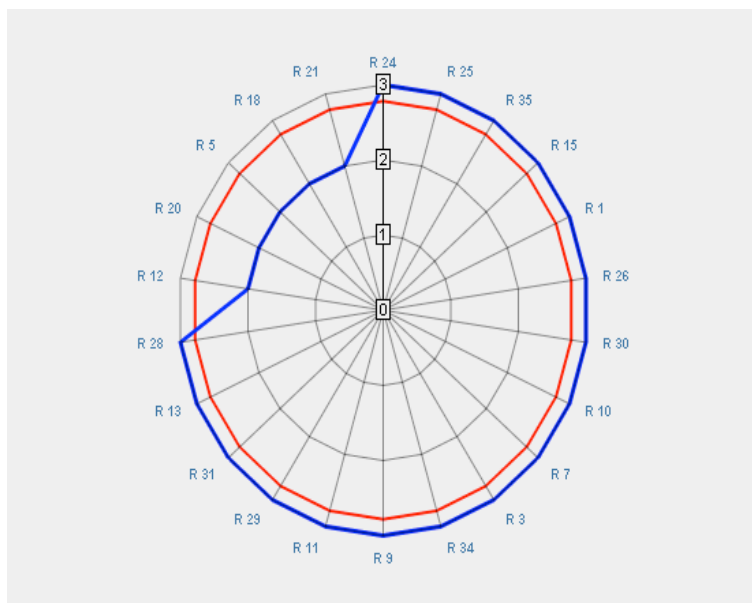
The following comments were received:-

“yes, this is a significant concern when it comes to the treatment of chronic diseases such as diabetes - notably with the transition of type 1 diabetes children to adolescent to adult hospital/clinical settings”

“very important and IT integration is fundamental”

“Seamless care is particularly important to avoid duplication, medication errors, etc.”

EAHP Members



Average score: 2.77

The following comments were received:-

"An integrated medicines management model in place will cover this topic and ensure a safe transition to the next level of care, with an updated and appropriate drug list."

"including recommendations to subsequent practitioners on appropriate monitoring etc."

"Totally agree. We must optimise all the steps of the pharmacotherapeutic trip of the patient and this step is source of a lot of 'errors'"

"Seamless care should be integral part of medication information system at secondary and tertiary hospital pharmacy level."

"the transfer of information about patient medication whenever they are moved between healthcare setting, is essential since it will contribute to provide safe/optimal continuation of treatment (less medication errors)"

"promote and implement medicine reconciliation process - this ensures seamless care - every transfer point of the patient"

"Strongly agree on the concept but as the resources are imitated, the activities of the pharmacist in Switzerland are for the moment more focused on the hospital stay. However, seamless care is highly important and developments in that field are necessary".

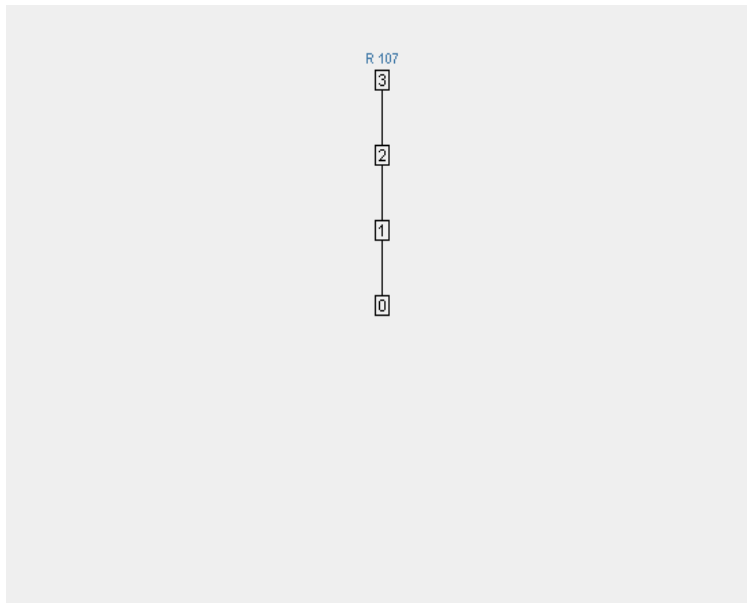
"Currently in our country it is almost impossible2

"Ideally, yes."

Conclusion: the comments do not suggest any revisions to the existing statement. No changes are proposed for Delphi 2:-

Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings.

Partner health organisations



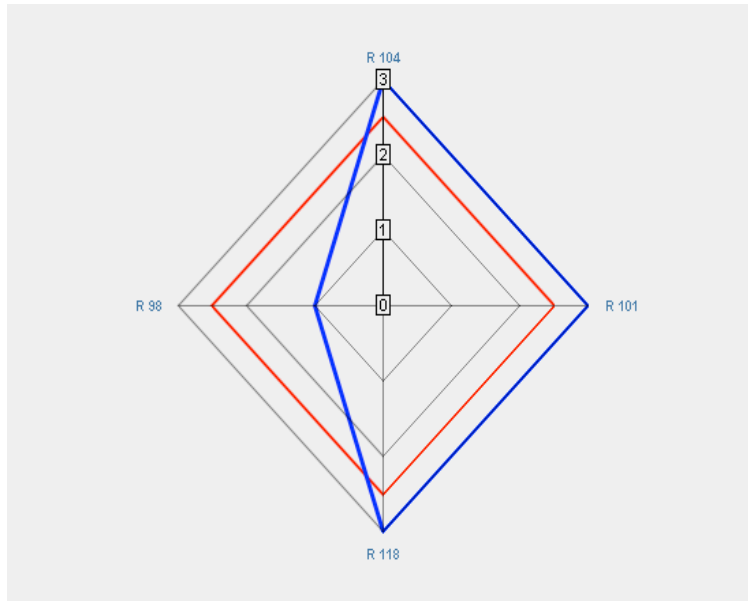
No significant comments were received from partner health organisations.

Action: No changes are proposed for Delphi 2:-

Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings.

4.6 Hospital pharmacists should ensure that patients are educated on the appropriate use of their medicines. (Statement 29).

Patient groups



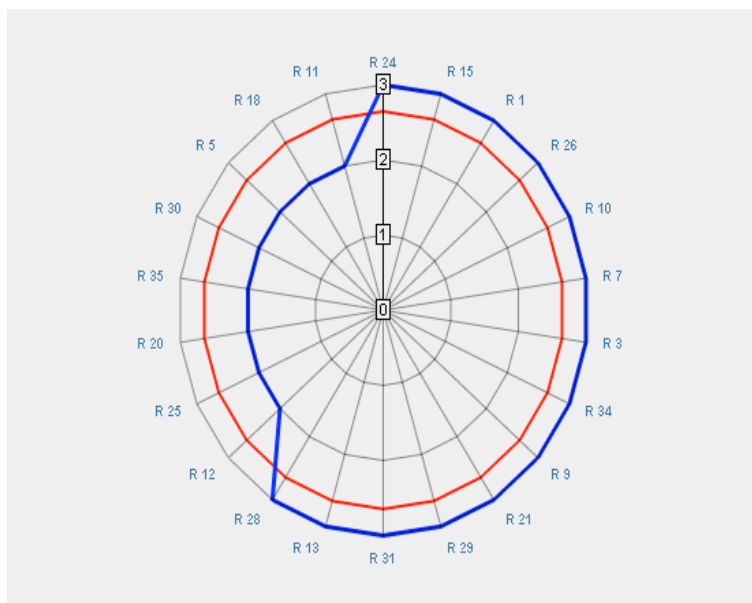
Average score: 2.5

The following comments were received:-

agree- however other staff members are also usually involved in this process of education (registered nurses/doctors), peer-to-peer support

Not sure this is the role of the HP.

EAHP Members



Average score: 2.64

The following comments were received:-

"This is one out of three extremely important components in optimizing drug therapy"

"and a wonderful opportunity to use other pharmacy professionals such as pharmacy technicians"

"Therapeutic Education is an important activity of a clinical pharmacist. This therapeutic education must be done in collaboration with the others health care professionals (Standardisation for all patients are concerned)"

"While I strongly agree with the principle, I seriously doubt its feasibility."

"I totally agree"

"Very important activity!"

"information delivery is a foundational activity of hospital pharmacist"

"A suggestion: Hospital pharmacists should ensure as part of the patient care team that patients are educated on the appropriate use of their medicines."

"I agree, but you must created a procedure in this sense."

"This should be done in collaboration with other healthcare professionals and is also one of the main responsibilities of community pharmacists"

"educated - this is a BIG word :) should we rather use given appropriate information and follow up"

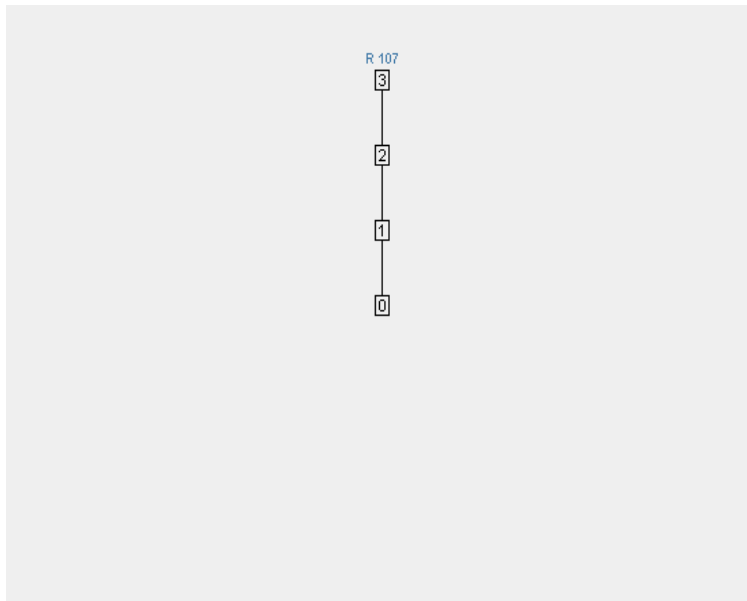
"Of course, I do agree with the term patient education. However, I would love to read a link to increased health literacy, as this is the ultimate goal - increased health literacy means also increased ability to manage him/herself"

"This is possible only if there is enough hospital pharmacists. If that is not the case an adequate information system should be provided to facilitate information dissemination."

Conclusion: taking all comments into account, some revision of the statement is possible to reflect the pharmacist as one member of the team caring for the patient, and also that the role is to provide information with patient autonomy still governing the decisions they make about their medicines. The following revision is proposed for Delphi 2:

As an integral part of all patient care teams, hospital pharmacists should ensure that patients are given appropriate information on the use of their medicines.

Partner health organisations



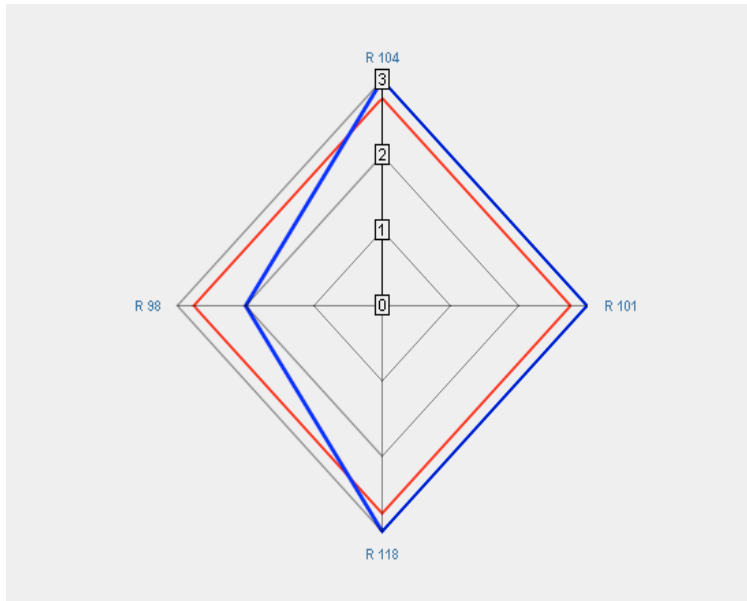
No significant comments were received from partner health organisations.

Action: revised statement for Delphi 2 is proposed:-

As an integral part of all patient care teams, hospital pharmacists should ensure that patients are given appropriate information on the use of their medicines.

4.7 Pharmacists should inform and advise on and oversee the use of medicines outside of their marketing authorisation (off label use). (Statement 30).

Patient groups

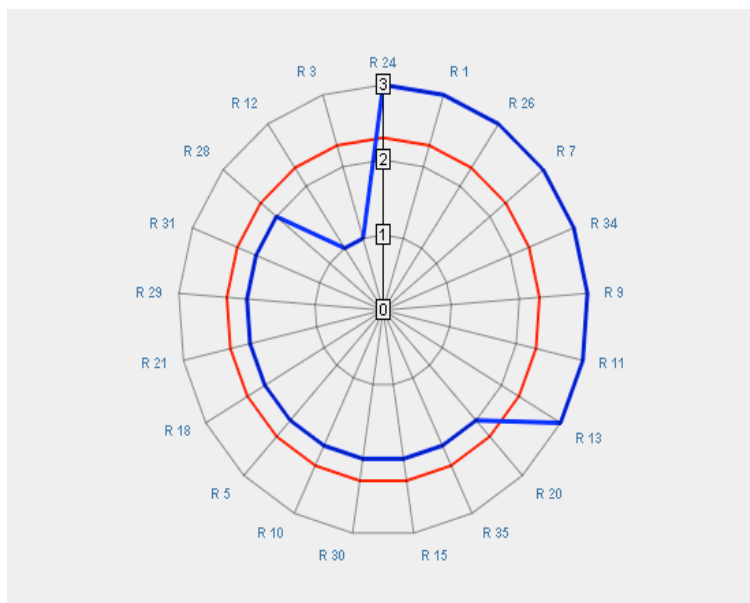


Average score: 2,75

One significant comment was received from patient groups.

“Yes, off label use is becoming more and more important, especially during economic crises.”

EAHP Members



Average score: 2,29

The following comments were received:-

"Hospital Pharmacists must inform about the "risk" of an off label use and moreover inform about the follow-up of a such use (active pharmacovigilance)"

"strongly agree..... and informed consent must be obtained"

"ok - not sure I follow this oversee - is this supervise ?"

"yes, but not only off-label use, also compassionate use programmes and early access programme should be under the auspices of the hospital pharmacist"

"I agree, especially as compassionate use progr and early access programmes seem to be on the rise and in many instances involve complex management."

*"In Norway the doctor is solely responsible for off-label use. Proposal on adjusted text: **"Pharmacists should inform and advise on the use of medicines outside of their marketing authorisation (off label use)."***

"But the doctor is solely responsible for off-label use."

"The medication regulations should force the pharmaceutical industry to obtain a marketing autorisation for frequent off-label indications".

"In my opinion the doctor is responsible for off-label use of medicines/including oversee the use/, the pharmacist only inform and advise the patient"

"It would mean a lot to add a little on documentation to be able to gather knowledge from the use of off-label use - to benefit further potential use: Pharmacists should inform and advise on and oversee the use of medicines outside of their marketing authorisation (off label use). Pharmacists should promote documentation of the use and outcome of off-label use to benefit evaluation of this and to provide more knowledge."

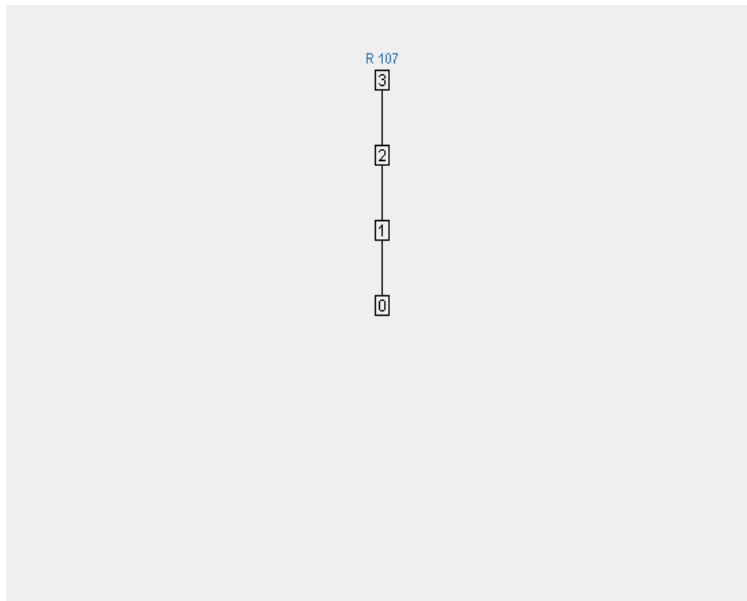
"I disagree."

"Off-label use is common in some areas (eg. Paediatrics) so not a high priority if team delivering evidence based practice. Marketing Authorisation is as it states provides the manufacturer with authority to promote not to restrict clinicians effective usage."

Conclusion: taking all comments into account, "oversee" seems to be problematic given the responsibility for off-label prescribing rests with the prescriber. The suggested Norwegian wording overcomes this and it is proposed to adopt this for Delphi 2:-

Pharmacists should inform and advise on the use of medicines outside of their marketing authorisation (off label use).

Partner health organisations



No significant comments were received from partner health organisations.

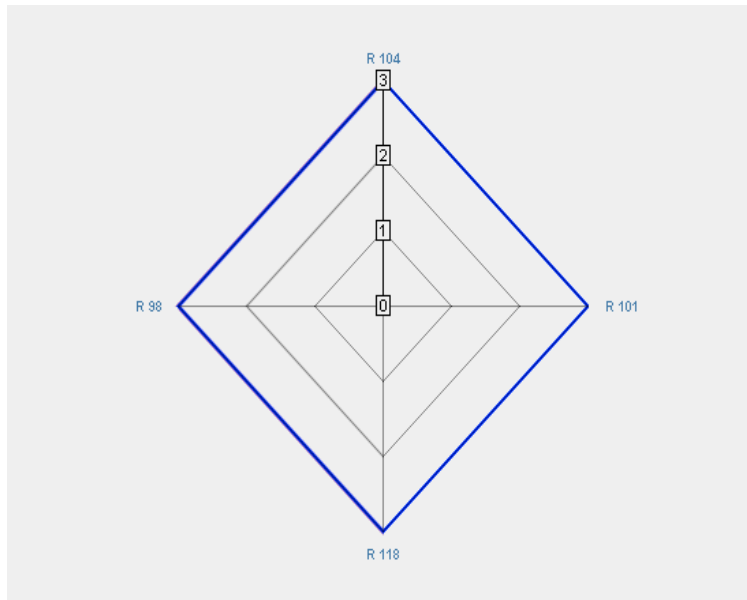
Action: proposed wording for this statement for Delphi 2 is:-

Pharmacists should inform and advise on the use of medicines outside of their marketing authorisation (off label use).

Aspect: Patient Safety and Quality Assurance

5.1 The “seven rights” (the right patient, right medicine, right dose, right route, right time, right information and right documentation) should be fulfilled in all medicines-related activities in the hospital. (Statement 31).

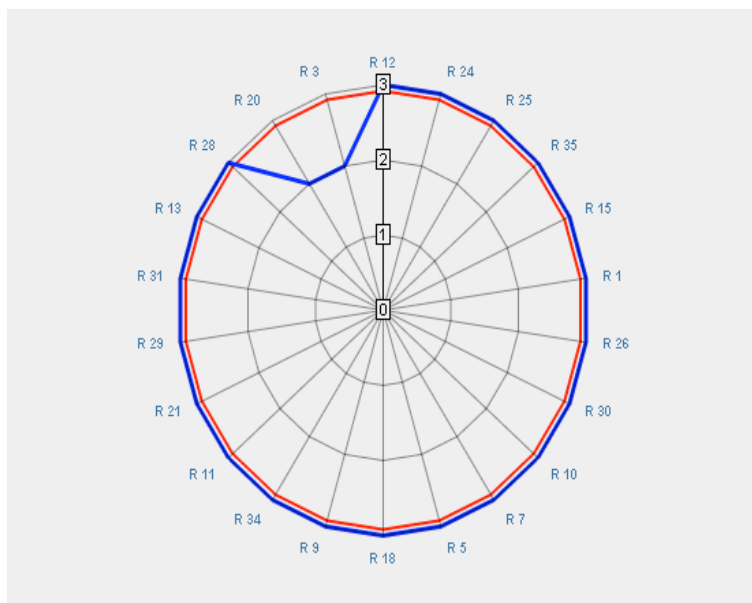
Patient groups



Average score: 3.0

No comments were made by patient groups.

EAHP Members



Average score: 2.91

This statement achieved excellent consensus and few comments were received:-

"Strongly agree with the STATEMENT itself, albeit not with the interpretation. The differentiation between patient, healthcare professionals, and hospital pharmacists remain blurry. They have to be distinct. The implementation of measures to guarantee adherence to the 7 "Rs" are more important than knowing the 7 "R's" themselves. The paragraph about documentation is misplaced in this paragraph."

"medicines-related activities = ?"

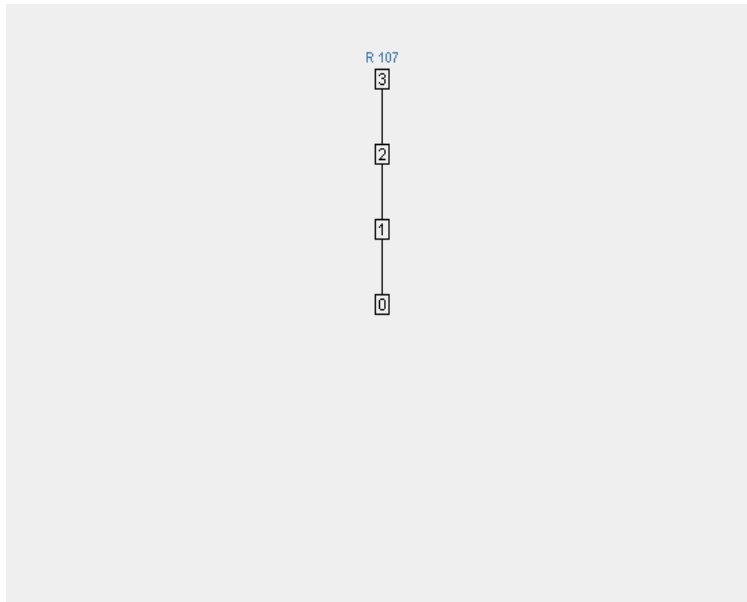
"in all areas of medication management or medication services ?"

"provided we accept the right of the patient to decline or reject the treatment is a fundamentally accepted right outside of these 7"

Conclusion: no changes are proposed for this statement for Delphi 2.

Note for moderators and EAHP: is "fulfilled" the right word, and what about "medicines-related activities"?

Partner health organisations



No significant comments were made by Partner health organisations.

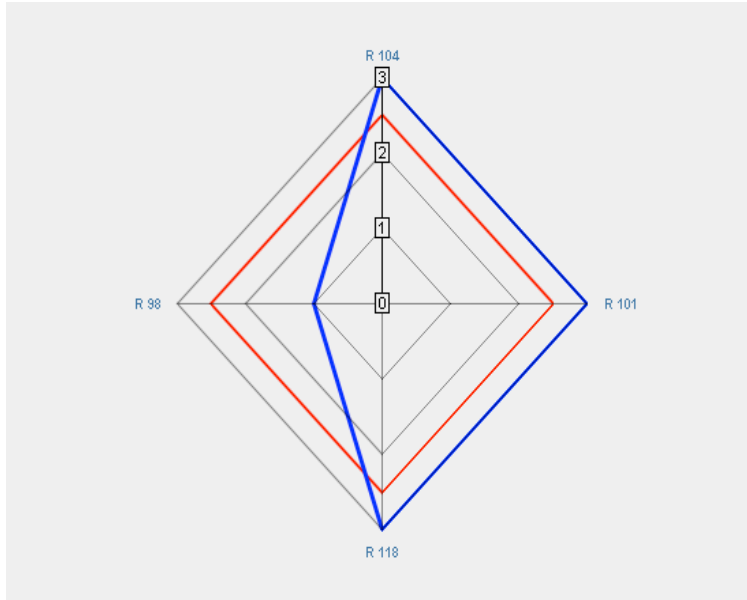
Action: no changes to this statement for the Delphi 2 process are proposed.

The “seven rights” (the right patient, right medicine, right dose, right route, right time, right information and right documentation) should be fulfilled in all medicines-related activities in the hospital.

Note for further discussion: can we reference the 10 “rights, or is it 7 “rights”? Andy found a few different versions with different numbers of rights, and mostly referring to administration rather than other medicines-related activities. I can see that they would apply to any chart review as well as administration but is this in the literature? Neal

5.2 Hospital medication practices should be reviewed by an external quality assessment accreditation program. Hospitals should act on reports following regular external quality assessment inspections to improve the quality and safety of their practices. (Statement 32).

Patient groups

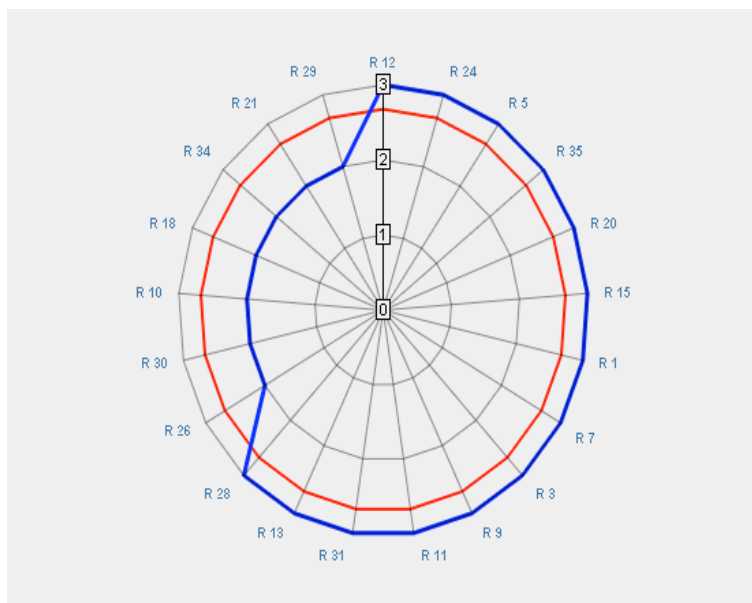


Average score: 2.5

One significant comment was made.

"Not sure that external quality assessment is necessarily the right method."

EAHP Members



Average score: 2.67

The following comments were made:-

"We strongly agree that external audits are an important tool. Internal processes altogether have to be assessed by EXTERNAL quality standards. However, in the arguments, internal and external activities are mixed up. The core business is left out. In addition, the paragraph focuses on clinical pharmacy, ignoring the important quality aspects of logistics."

"have to accept you cannot inspect for quality. Quality is based on professionalism of the system owners could be reworded to state hospitals consider and if appropriate act on reports"

"External quality assessment accreditation programme should take into account different level of hospital medication practices in each hospital. In other words it should help improving hospital medication practices through accreditation programme".

"But at least in my country there is no such accreditation program available...Do you want to say with this statement that hospital pharmacy (and services) should have accreditation? Or hospitals medication practices? I think that quality assurance and external assessment for both is needed. If you have hospital pharmacist working in the unit, is it internal or external assessment?"

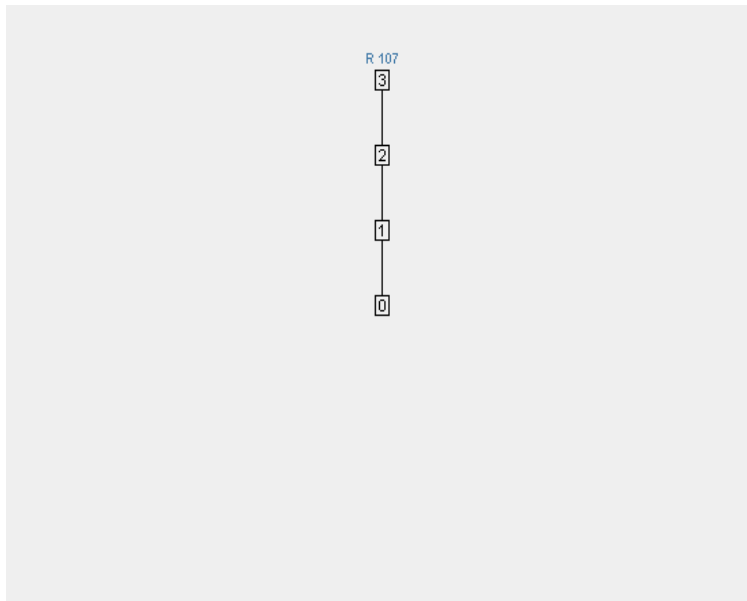
"Hospitals should seek review of their medication practices by an external quality assessment accreditation programme. Hospitals should act on reports as appropriate to improve the quality and safety of their practices"

"I think it's a good way to continue to improve our activities. As Hospitals are in our country inspected by the government, it is the government that insists to step in an accreditation program. Within that accreditation process, the hospital pharmacists practices are included."

Conclusion: the suggested re wording will hopefully clarify the statement and is proposed for Delphi 2.

Hospital medication practices should be reviewed by an external quality assessment accreditation program. Hospitals should act on reports following regular external quality assessment inspections to improve the quality and safety of their practices

Partner health organisations



No significant comments were made by partner health organisations.

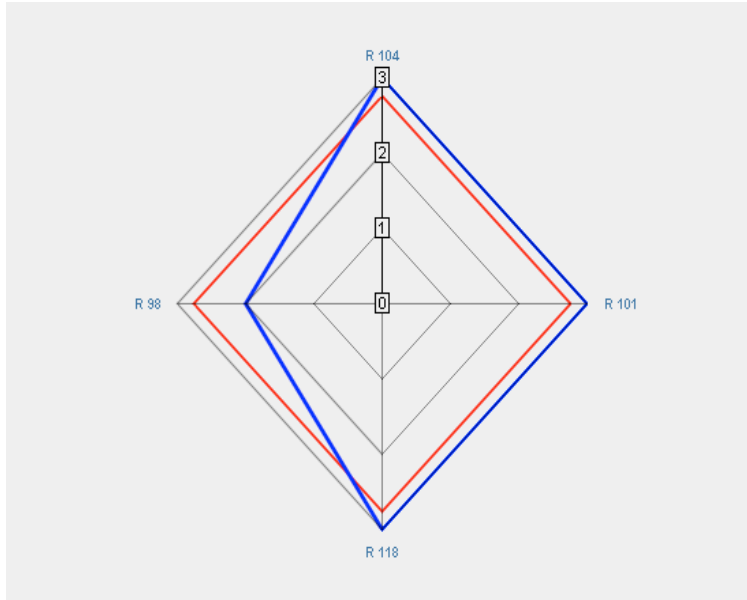
Action: the suggested re wording will hopefully clarify the statement and is proposed for Delphi 2.

**Hospitals should seek review of their medication practices by an external quality assessment accreditation programme.
Hospitals should act on reports as appropriate to improve the quality and safety of their practices.**

Note for moderators and EAHP: is external quality assessment a topic for a Barcelona workshop?

5.3 Hospital pharmacists should ensure the development of quality assurance strategies for medication practices, including the use of observation methodology and Clinical Incident Reporting System (CIRS) to detect errors and identify priorities for improvement. (Statement 33).

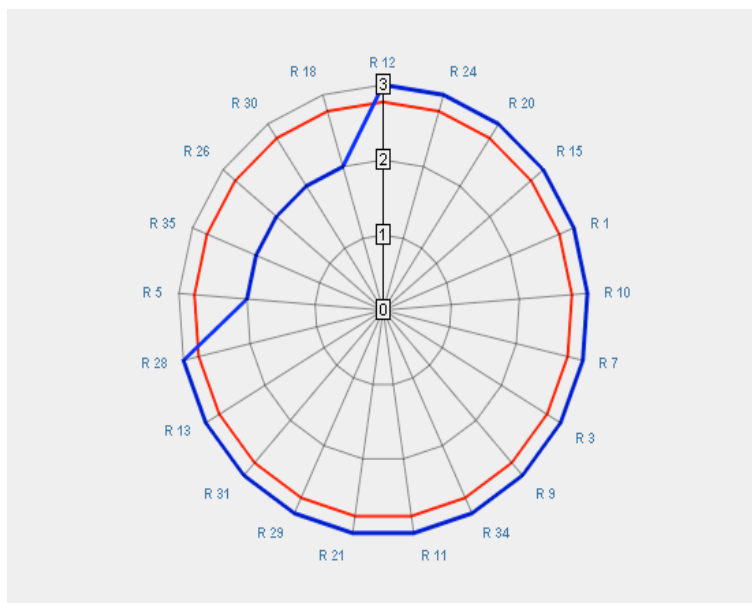
Patient groups



Average score: 2.75

No significant comments were made by patient groups.

EAHP Members



Average score: 2.76

MERS deal with medications themselves, but CIRS deals also with devices and atc.....am I right? Could it be also added "for medical devices"?

This will be hard to achieve.

The quality wheel/loop: Plan-Do-Check-Act

Only when we know what is going wrong, we can continuously improve our systems. I cannot imagine a Hospital system that says: from now on, we never go wrong anymore because in a hospital you work with people and people will always make errors and systems will always have weaknesses

Medication error reporting should be made mandatory.

The Hospital as a whole needs a quality improvement strategy, hospital pharmacists take an important role. However, the driving force has to be "top-down". The hospital pharmacists should not be in the center of this statement. The role of the hospital pharmacist can be emphasized in the column "hospital pharmacist".

not only to detect already manifest errors, but also take prevention measures if deemed necessary as a result of observations or reports from CIRS

But I think that in many countries we dont speak about CIRS. Medication error reporting systems (MERS) is more used term.

We should speak reporting medication errors (rather than just errors).

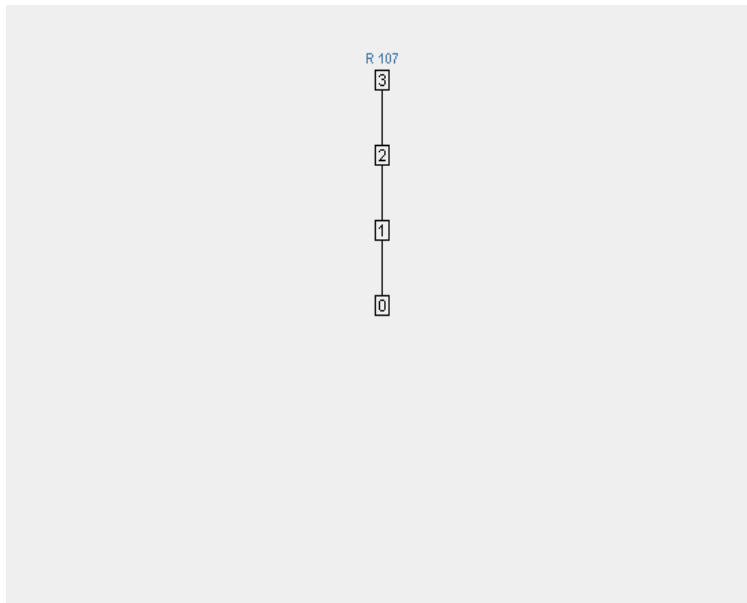
I don't understand what means "Hospital pharmacists should develop simple rules-based approaches to advancing patient safety".

Observation methodology should be included also to explanation texts.

Conclusion: adding in Medication Error Reporting Systems (MERS) to the statement should increase the consensus further in Delphi 2.

Hospital pharmacists should ensure the development of **appropriate quality assurance strategies for medication practices including the use of observation methodology, Medication Error Reporting Systems (MERS), and Clinical Incident Reporting System (CIRS) to detect errors and identify priorities for improvement.**

Partner health organizations



No significant comments were made by partner health organisations.

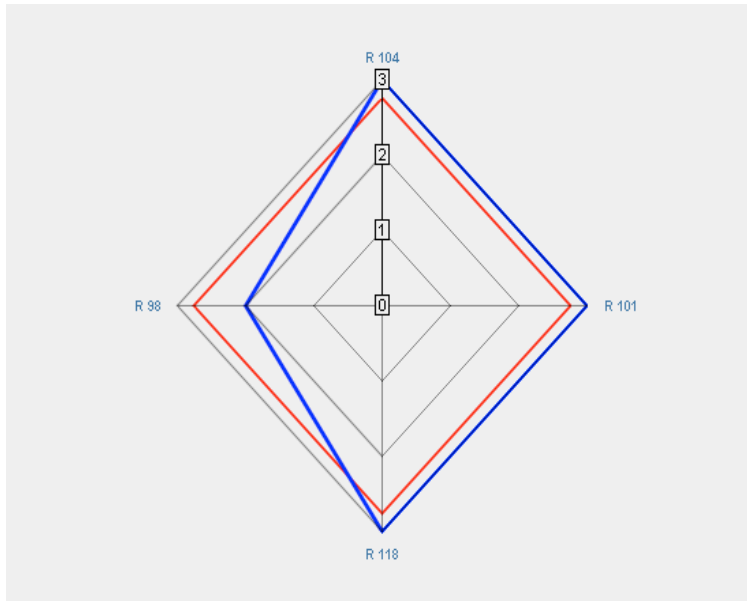
Action: adding in Medication Error Reporting Systems (MERS) to the statement should increase the consensus further in Delphi 2.

Hospital pharmacists should ensure the development of **appropriate** quality assurance strategies for medication practices including the use of observation methodology, Medication Error Reporting Systems (MERS), and Clinical Incident Reporting System (CIRS) to detect errors and identify priorities for improvement.

Note to moderators and EAHP: is this another topic for a Barcelona workshop?

5.4 Hospital pharmacists should decrease the risk of medication errors by implementing evidence-based systems or technologies systems. (Statement 34).

Patient groups

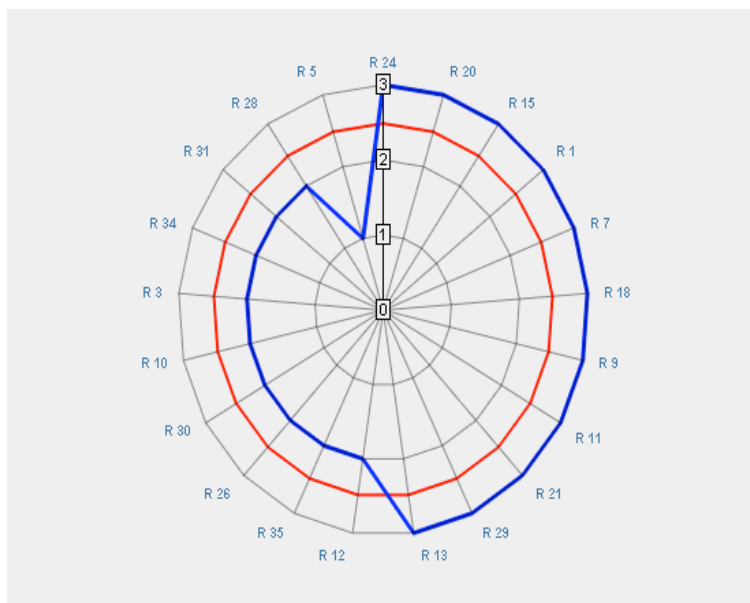


Average score: 2.75

One significant comment was made:-

"Not sure whether evidence-based is always 'true'."

EAHP Members



Average score: 2.48

The following comments were received:-

“we are to be involved but need other professions to lead this work like IT people with experience within health care technology”

“Is this area covered in pharmacy programs at the Universities? Should the curriculum be revised to support this statement?”

“evidence-based systems - this is a vague term - could this be made more clearer or more explicit”

“Patient explanation text should have some patient perspective...Healthcare professionals explanation text I don't find the role or impact of pharmacists.”

“it should be worded after implementing cost effective evidence based systems including ‘technology’ “

“additionally provided this is on a risk based approach to maximize benefit”

*“The hospital pharmacist **must be involved** in an IT implementation to decrease the risk and of course, Hospital Direction must give human/technology resources to the Hospital Pharmacy to implement a such program”*

“Information Technology can really prevent medication errors and where possible we must implement such a system”

*“Suggestion of adding a word: Hospital pharmacists should **help** decrease the risk of medication errors by implementing evidence-based systems or technologies systems”*

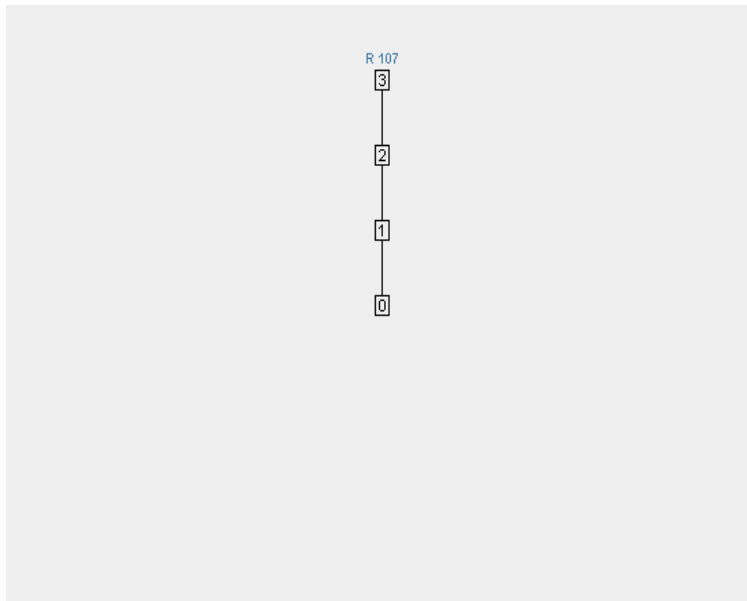
“Hospital pharmacists play an important role in implementing clinical information systems. However, the hospital pharmacist is not necessarily the leader in implementing IT measures. The statement should be rewritten in the sense that evidence-based technology should be applied to improve medication safety. The statement needs to be written in a more general way, not centering on hospital pharmacists.”

Conclusion: rewording to reflect the required multi-dimensional approach should help clarify and improve consensus in Delphi 2.

The following revision is proposed:-

Hospital pharmacists should help to decrease the risk of medication errors by disseminating evidence-based approaches to error reduction including computerised decision support.

Partner health organisations



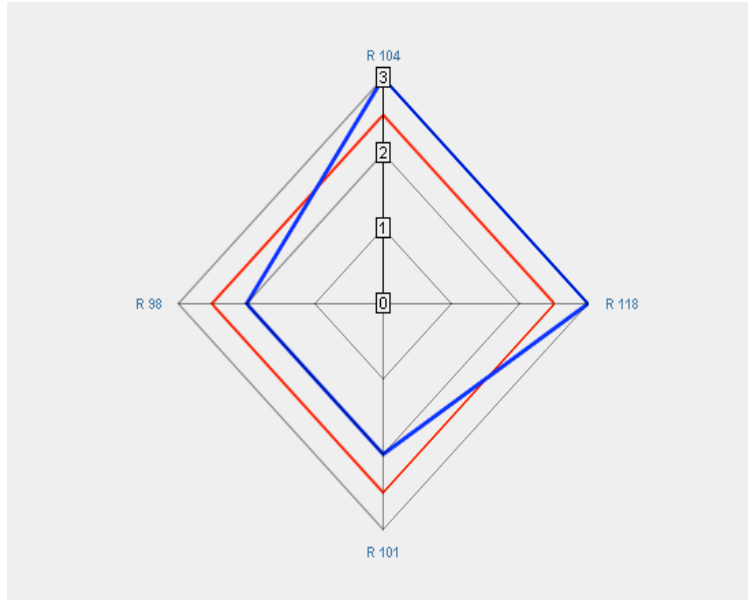
No significant comments were made by partner health organisations.

Action: the following revision is proposed for Delphi2:

Hospital pharmacists should help to decrease the risk of medication errors by disseminating evidence-based approaches to error reduction including computerised decision support.

5.5 The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated. (Statement 35).

Patient groups



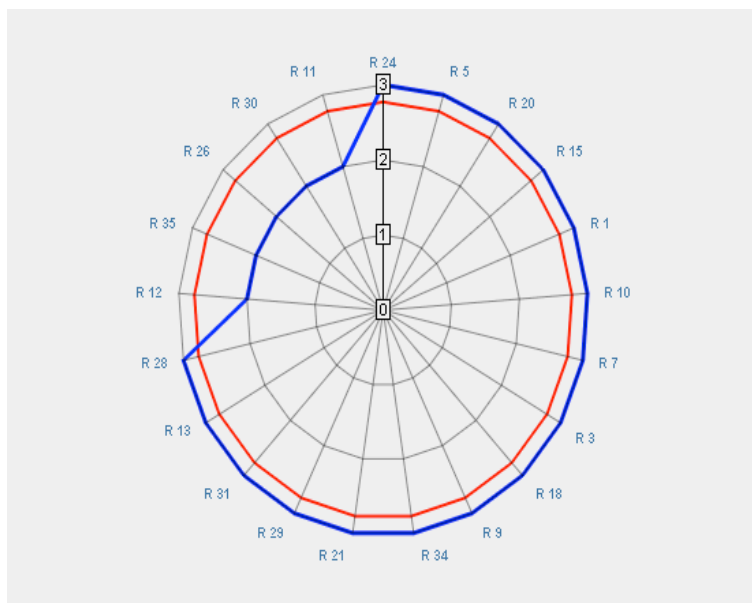
Average score: 2.5

Two comments were received:-

"To me the sentence is not very clear"

"Yes, that way the margin of error will decrease."

EAHP Members



Average score: 2.76

The following comments were received:-

"yes - no paper only electronic systems should be used"

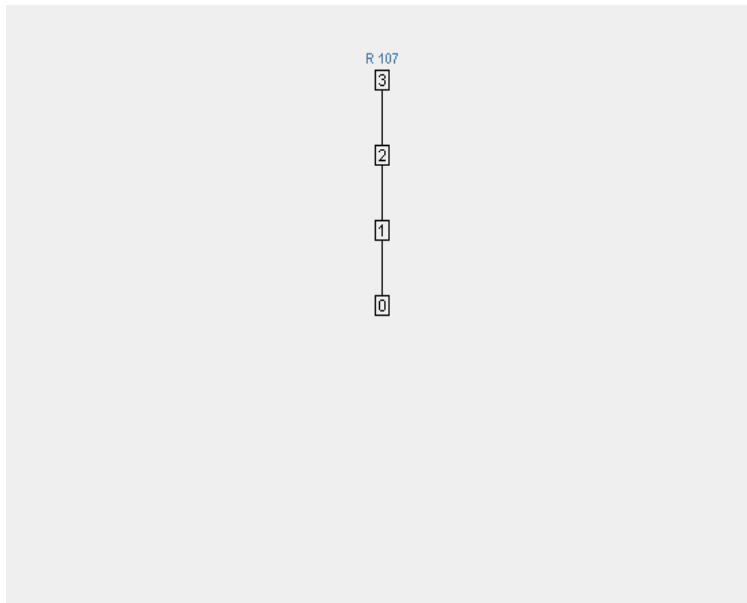
"and if they are not eliminated, hospital pharmacy must optimise this transcription step (for example to give information/training about "How can we Good Prescribe"...). Elimination must indeed be a goal. With an electronic prescribing system this is the case, but even with a paper prescribing system, this can work"

"errors at all transcriptions stages should be removed."

Conclusion: there is very good consensus on this statement already and current wording does not require further clarification. No changes are therefore proposed to this statement for Delphi 2.

The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated

Partner health organisations



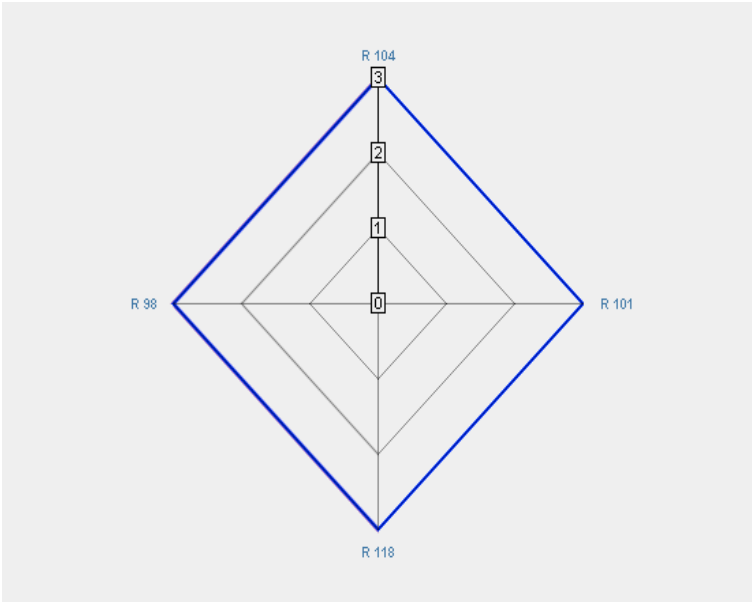
No significant comments were received from partner health organisations.

Action: no changes are proposed to this statement for Delphi 2.

The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated.

5.6 High risk medicines should be identified and appropriate procedures implemented that assure checks prior to dispensing and administration. (Statement 36).

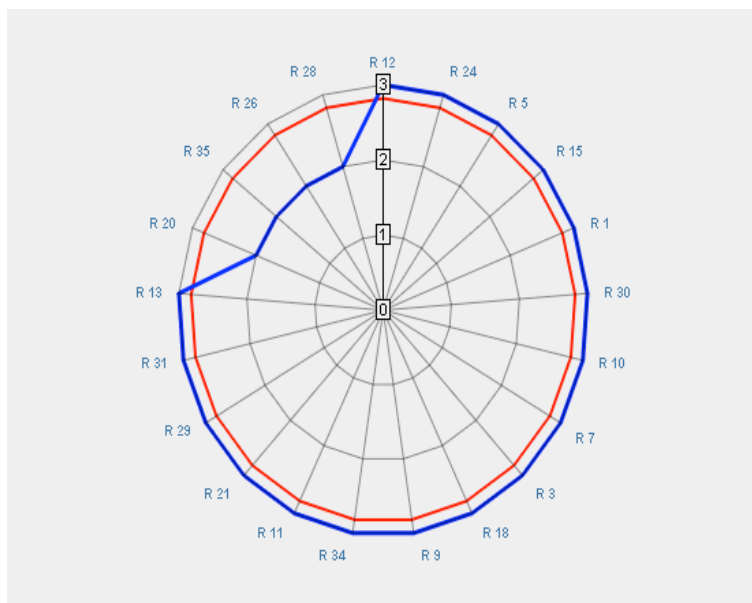
Patient groups



Average score: 3.0

No significant comments were made by patient groups.

EAHP Members



Average score: 2.81

The following comments were received:-

"We strongly support the idea of identifying high risk medicines and procedures for every individual institution."

"This (procedures) should be well discussed and elaborated at Drug and Therapeutic Committees and supported by all health care professionals."

"prior to prescribing, dispensing and administration"

"often these meds are prescribed and given before we have the chance to check !"

"suggestion: 'High risk medicines should be classified and identified, and appropriate procedures implemented that assures appropriate prescribing and check prior to dispensing and administration"

"prior to prescribing, dispensing, administration.. should be amended"

"prescribing should be amended - checks for high risk medicines should also take place at the time of prescribing, not only at dispensing, preparation and administration."

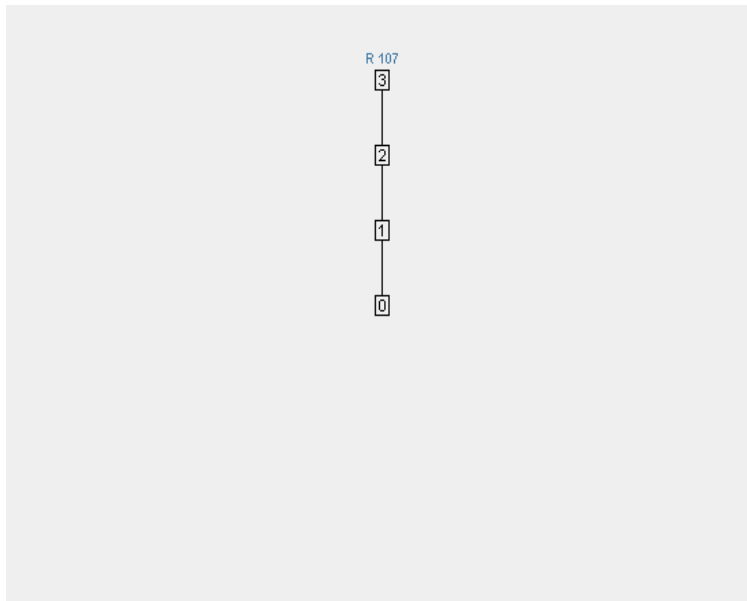
"Does this statement include sound and look-alike medicines? The role of pharmacists is to identify high risk medicines and to create practices that prevent high risk errors (this should be also in healthcare professionals explanation text)."

"Is it possible that high risk medicines are approved by pharmacists prior administration? Some of the high risk medicines are used in emergency department or surgery."

Conclusion: although the consensus is already excellent, adding "prescribing" would potentially increase it in Delphi 2.

High risk medicines should be identified and appropriate procedures implemented that assure checks prior to prescribing, dispensing and administration.

Partner health organisations



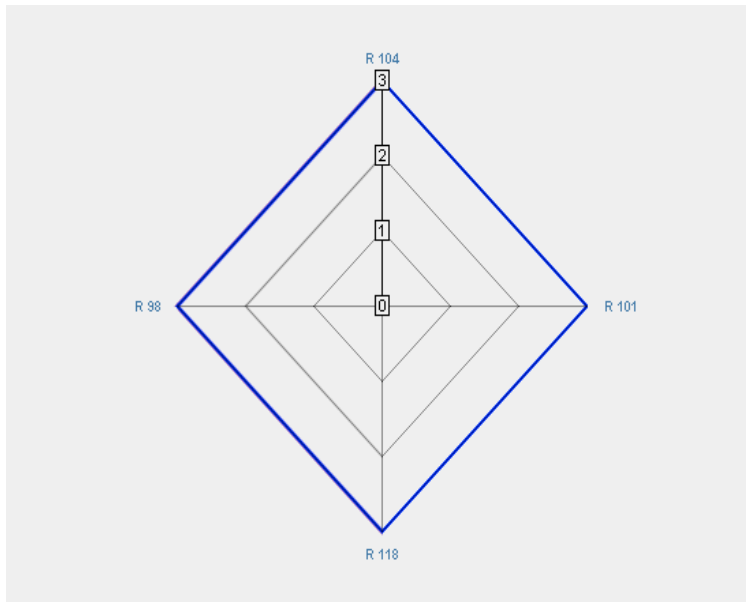
No significant comments were received from partner health organisations.

Action: the following revision is proposed for Delphi 2:

High risk medicines should be identified and appropriate procedures implemented that assure checks prior to prescribing, dispensing and administration.

5.7 Hospital pharmacists should ensure that medicines stored throughout the hospital are packaged and labelled so to assure identification, maintain integrity until immediately prior to use and permit correct administration. Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured through the whole process from production to administration. (Statement 37).

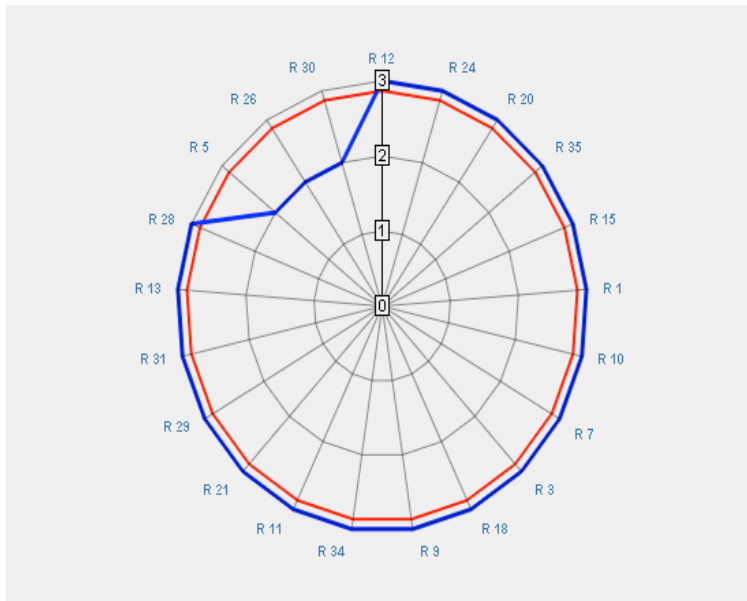
Patient groups



Average score: 3.0

No significant comments were received from Patient groups.

EAHP Members



Average score: 2,86

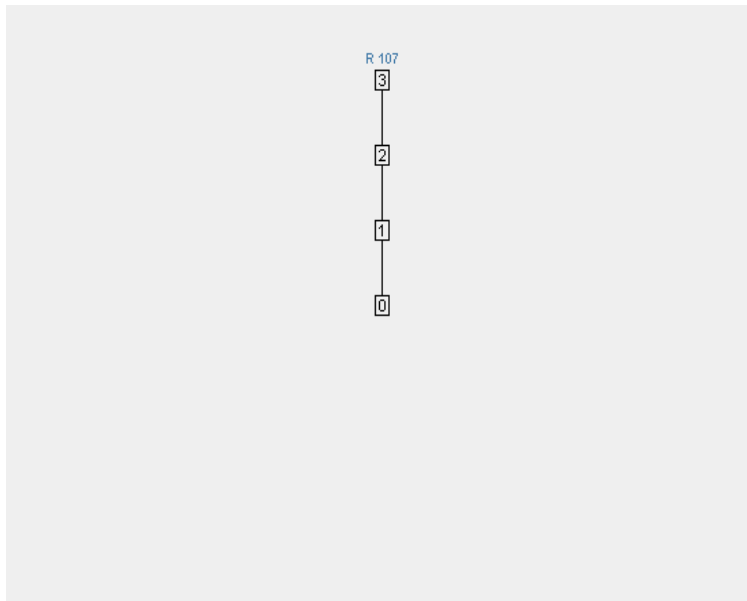
Consensus was excellent for this statement and only one significant comment was received.

"It should be emphasized that the hospital pharmacist plays an important role in the medication use process ON THE WARD. The hospital pharmacist should be leading efforts to establish guidelines for medication use on the wards."

Conclusion: no revision is required for Delphi 2.

Hospital pharmacists should ensure that medicines stored throughout the hospital are packaged and labelled so to assure identification, maintain integrity until immediately prior to use and permit correct administration. Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured through the whole process from production to administration.

Partner health organisations



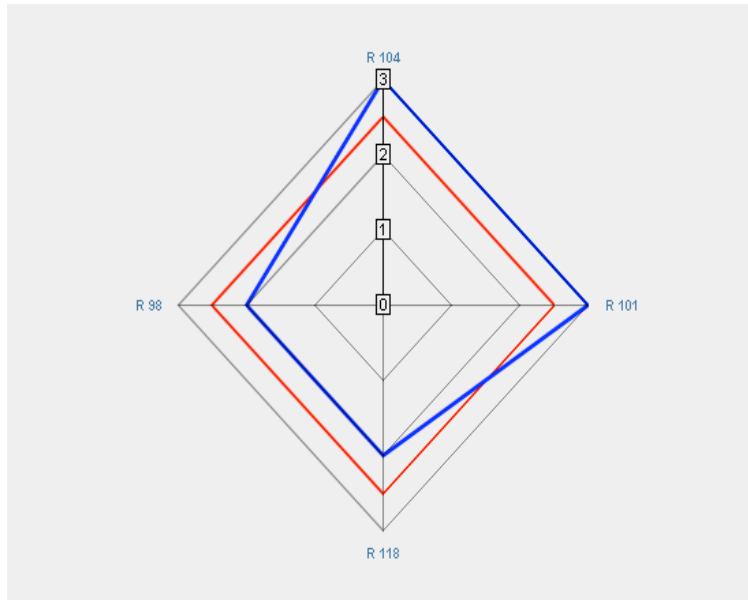
No significant comments were received from partner organisations.

Action: no revision is required for Delphi 2.

Hospital pharmacists should ensure that medicines stored throughout the hospital are packaged and labelled so to assure identification, maintain integrity until immediately prior to use and permit correct administration. Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured through the whole process from production to administration.

5.8 Hospital pharmacists should promote the reporting of adverse drug reactions and the forwarding of these to regional or national pharmacovigilance reporting programs where these are available. The monitoring data should be regularly reviewed to improve the quality and safety of medication practices. (Statement 38).

Patient groups



Average score: 2.5

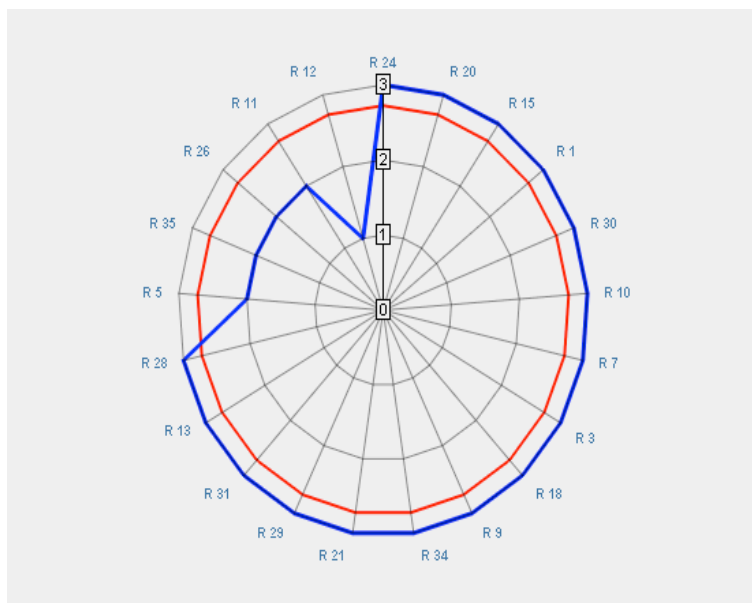
The following comments were received from patient organisations:-

“yes , but avoiding duplication of action and messaging as doctors or patients may also do this”.

“Pharmacists should actively encourage patients to report adverse drug reactions and to seek advice. Often, patients just stop taking the drugs.”

“and why not EU vigilance reporting?”

EAHP Members



Average score: 2.71

The following comments were received:-

"For this activity pharmacists need collaboration with other medical staff"

"A part of continuous learning and development of patient safety. Is it time to launch learning collaboratives managed by the hospital pharmacist?"

"including as practitioners submitting these reports themselves"

"ok, hospital pharmacists can promote the reporting of ADRs, but the authorities must search for a system that helps promoting the physicians, because it is not the hospital pharmacist that sees the ADR"

"Yes, but in collaboration with other medical staff."

"The meaning of "monitoring data" is not clear - please specify. Monitoring data applies better to critical incident reporting data. Adverse drug event data ore moreover CIRS data needs to be reviewed in a multi-disciplinary setting. The roles of national pharmacovigilance centers and hospital pharmacists are totally different."

"What is meant by regular review? is meant in-hospital review? otherwise review is not possible, because national data are not available in all countries and are only published as summary reports."

"Furthermore: the pharmacovigilance legislation does not only talk about the reporting of ADR itself, but also of medication errors to be reported. This should be amended or reflected in a way"

"I agree that pharmacists should promote reporting of adverse drug events but the analysis of those should be mainly on the responsibility of authorities because there is need for national level analysis. When the authorities will make recommendations according to that data, hospital pharmacists should (with other healthcare professionals) implement those to medication practices."

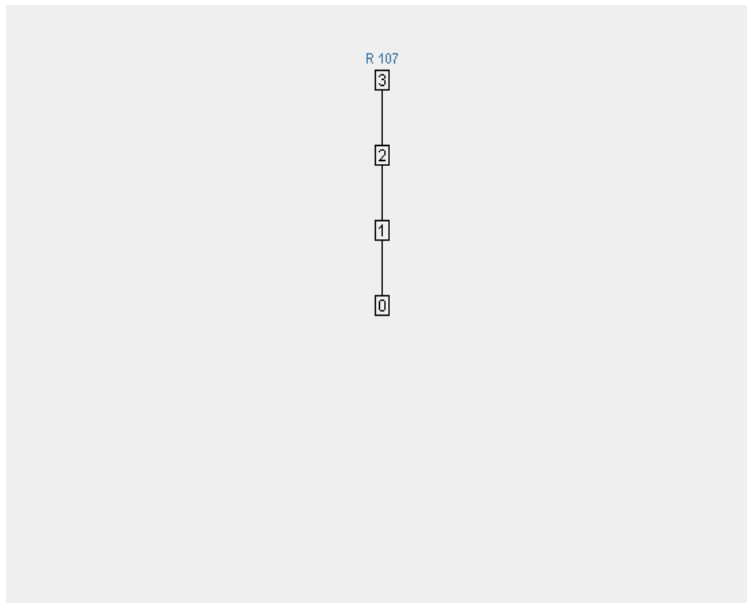
"Adverse drug reactions promotion programmes should be always supported by hospital pharmacists regardless of availability of such reporting programmes."

"I disagree. In our country, physicians report these things and are published in the Journal of pharmacovigilance."

Conclusion: based on the comments, since the responsibility for analysing reports rests with regional or national authorities, it is proposed that the second sentence in this statement is revised for Delphi 2.

Hospital pharmacists should promote the reporting of adverse drug reactions to regional or national pharmacovigilance programmes.

Partner health organisations



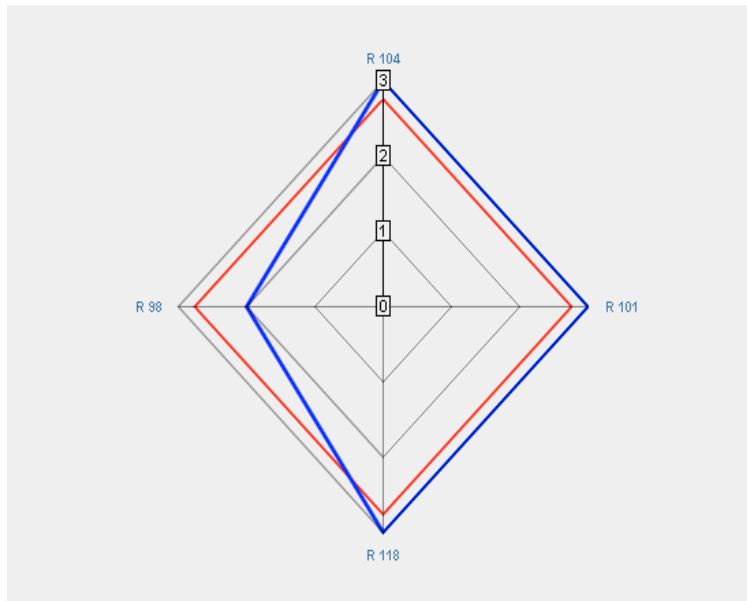
No significant comments were received from partner health organisations.

Action: it is proposed that the second sentence in this statement is revised for Delphi 2:-

Hospital pharmacists should promote the reporting of adverse drug reactions to regional or national pharmacovigilance programmes.

5.9 Hospital pharmacists should promote accurate recording of all allergy information in the patients' health record. This information should be accessible and evaluated prior to prescription and administration of medicines. (Statement 39).

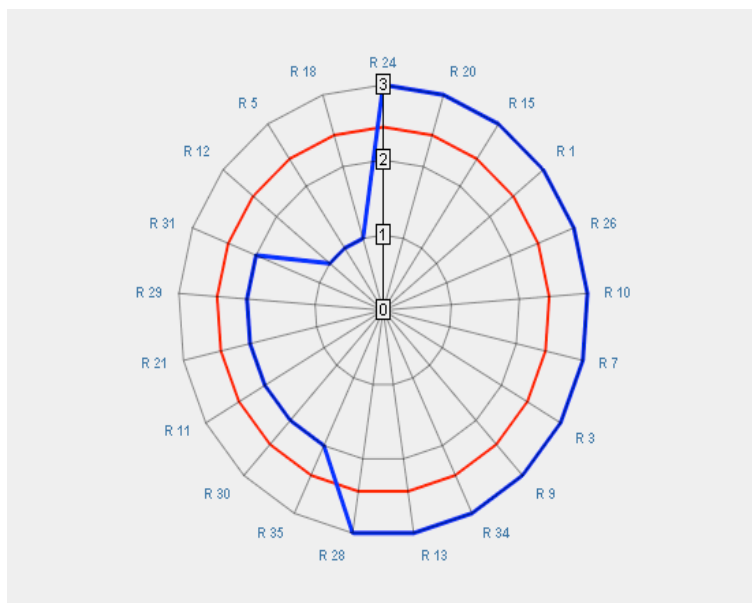
Patient groups



Average score: 2.75

No significant comments were received from patient groups.

EAHP Members



Average score: 2.43

"Very important for patient safety"

"But the recording of allergy information has been in the realm of admission medication reconciliation which is done by physicians and nurses so far."

"Do we mean adverse drug reactions rather than contraindications they should be included as they are different but important in the management of the patient and often confused."

*"This information should be accessible and evaluated via **information systems** prior to prescription and administration of medicines."*

"It should be the doctors' responsibility to record allergy data in the patients' health record. I think, pharmacists should only check this during the dispensing process."

"important for patients and HP too2"

In my opinion this is the doctor's responsibility.

"I disagree."

"The statements should be more general, not starting in any case with "the hospital pharmacist should....". Importantly, the recording of allergy information in Europe is mostly in the realm of admission medication reconciliation, which is done mostly by physicians and nurses."

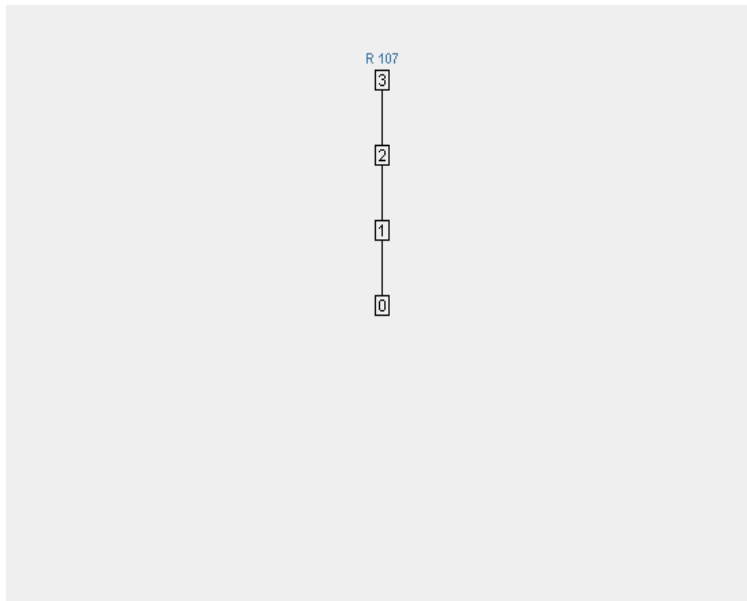
"This is the task of physicians"

Conclusion: a number of comments disagree with the statement on the basis that recording allergy information is the responsibility of nurses or doctors. However, this statement encourages pharmacists to PROMOTE the recording of allergy information. This promotion may be to the nurses or doctors, or to pharmacist colleagues. The important issue is that routine recording of allergies on admission takes place and this information is readily available to prescribers and when medicines are administered.

Hopefully, this explanation will help reviewers in Delphi 2. Revision of the statement is not required.

Hospital pharmacists should promote accurate recording of all allergy information in the patients' health record. This information should be accessible and evaluated prior to prescription and administration of medicines.

Partner health organisations



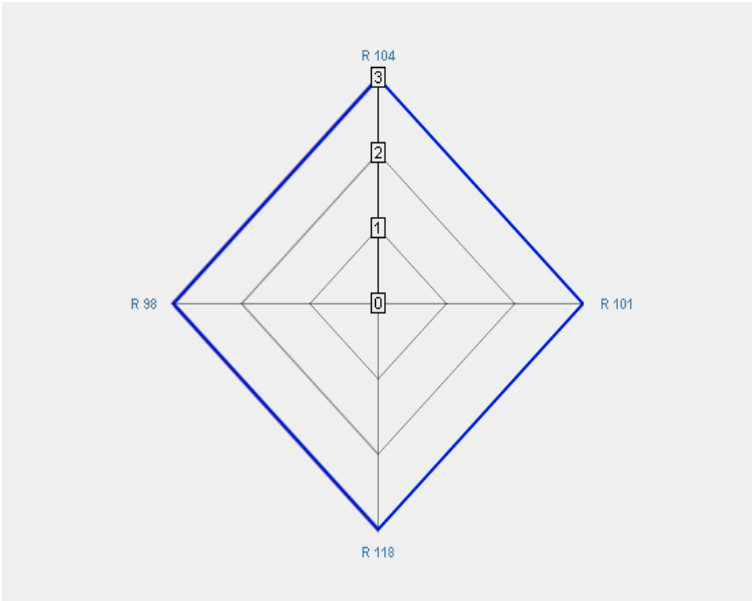
No significant comments were made by partner health organisations.

Action: Revision of the statement is not required for Delphi 2.

Hospital pharmacists should promote accurate recording of all allergy information in the patients' health record. This information should be accessible and evaluated prior to prescription and administration of medicines.

5.10 Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy. (Statement 40).

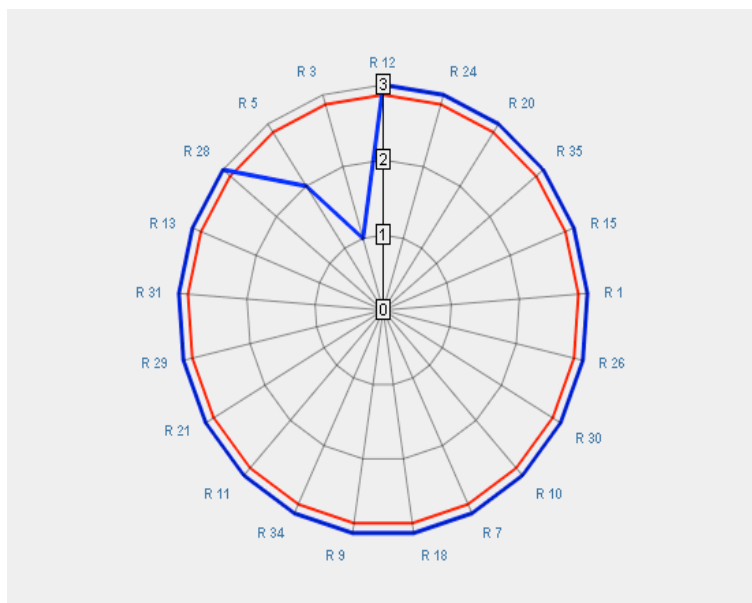
Patient groups



Average score: 3

No significant comments were received from patient groups.

EAHP Members



Average score: 2.86

But I am not quite sure if this is right place for the statement...would it be better under topic II Selection, Procurement and Distribution.

it's very important but we there is different degree of traceability...Without a 2D barcode, it is very difficult to have a traceability that goes to the patients administration

This statement is very similar to no. 22 although 22 is only about medicines produces in the pharmacy. Either a sentence similar to 22 could be added to the procurement and distribution' section or one common sentence on traceability should be included in this section.

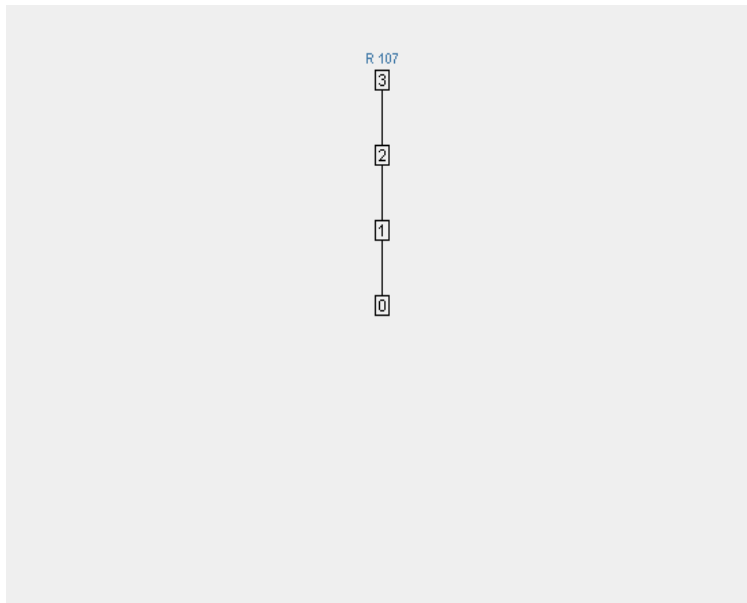
Traceability is important. However, it remains unclear on which level traceability is achievable. As long as datamatrix-barcoding is not consistently established, batch numbers can not be easily matched to patients.

not currently convinced this is currently worth the benefits against the costs if other systems in the supply chain are in place

Conclusion: Excellent consensus is already achieved and comments to not suggest a viable improvement. No change is proposed to this statement for Delphi 2.

Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.

Partner health organisations



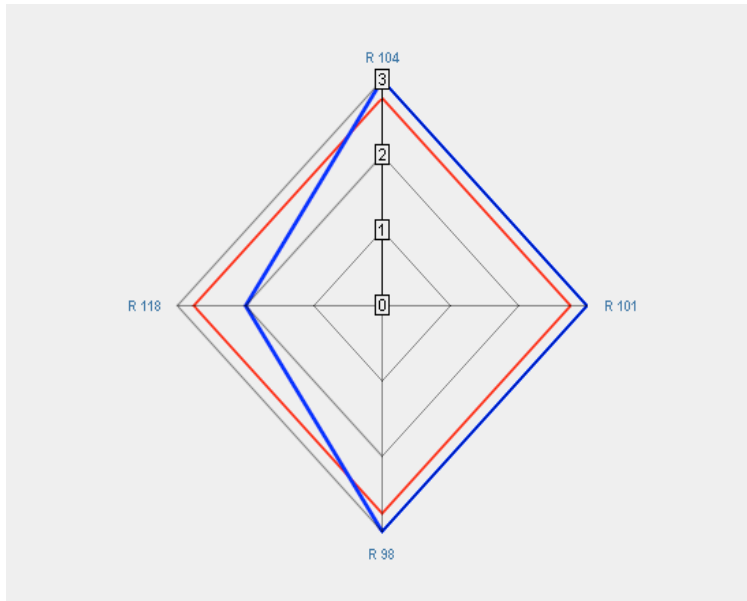
No significant comments were received from partner health organisations.

Action: no change is proposed to this statement for Delphi 2.

Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.

5.11 Hospital pharmacists should ensure that the information resources needed for safe medicines use, preparation and administration are accessible at the point of care. (Statement 41).

Patient groups

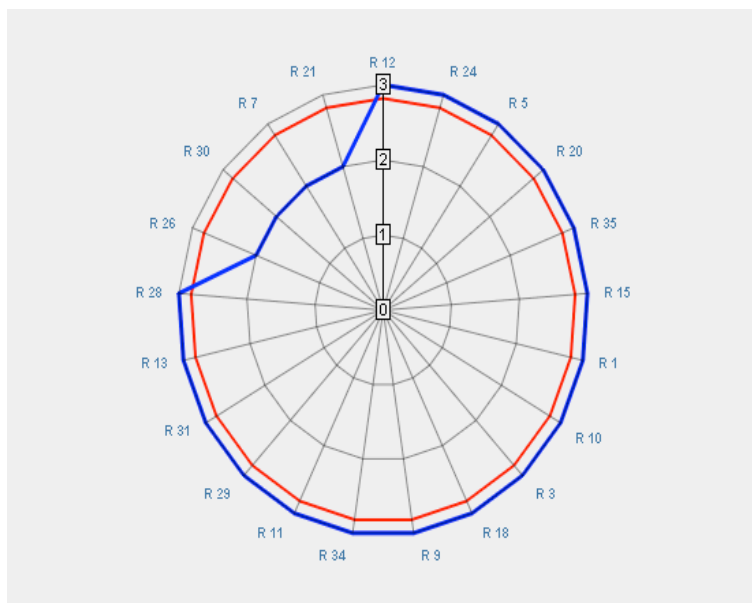


Average score: 2.75

One significant comment was received from patient groups:-

... and are available in a format readily understandable by patients

EAHP Members



Average score: 2.81

as mentioned in another statement, hospital pharmacy is the center of information (indications, preparation...) and this information must be available for every health care professionals of the hospital.

The information resources should be accessible at the point of care only if there is someone " trained healthcare professional" who can interpret this information in a proper manner.

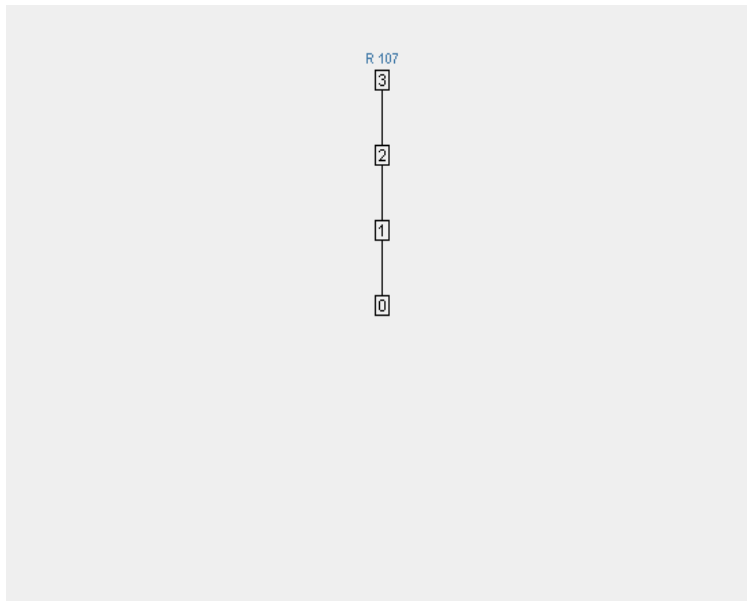
Hospital pharmacists should also produce actively medication information for other healthcare professionals and patients (e.g. summaries of many different references or recommendations). Recommendations written by pharmacists should not be limited on specific medicines, it can concern also services, systems, technologies, processes...

The pharmacist should contribute to these information activities but the responsibility should be at the drug and therapeutics committee at the hospital

Conclusion: taking all the comments into account, this statement already has excellent consensus and revision is not proposed. The availability for information in a format readily accessible by patients is an important point, but given current availability across a number of countries, the inclusion of this in the statement is unlikely to improve consensus.

Hospital pharmacists should ensure that the information resources needed for safe medicines use, including both preparation and administration, are accessible at the point of care.

Partner health organisations



No significant comments were received from partner health organisations.

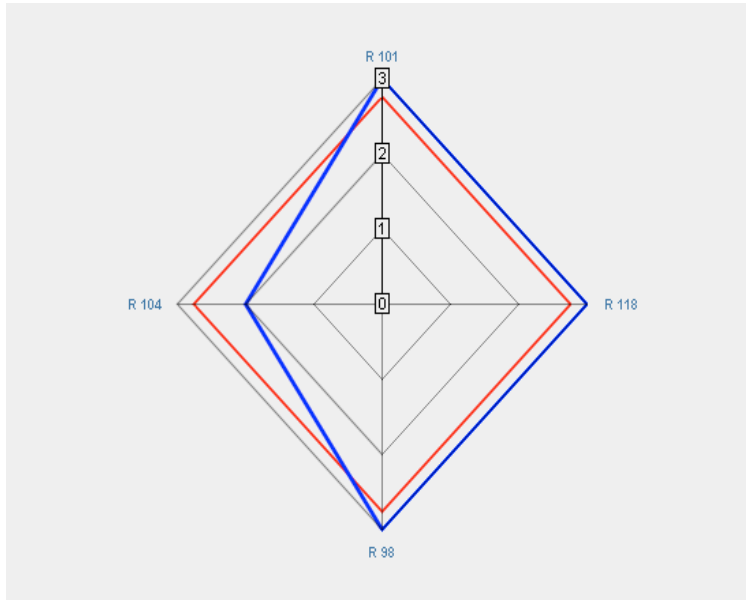
Action: revision of this statement is not proposed for Delphi 2.

Hospital pharmacists should ensure that the information resources needed for safe medicines use, including both preparation and administration, are accessible at the point of care.

Aspect: Education and Research

6.1 Undergraduate pharmacy curricula should include an introduction to hospital pharmacy practice. The role of hospital pharmacists should be promoted in the curricula of other health professionals. (Statement 42).

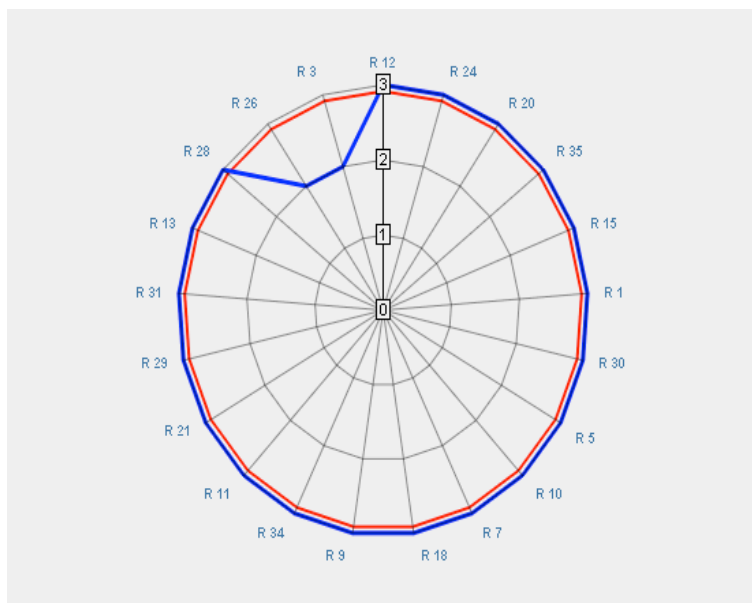
Patient groups



Average score: 2.75

No significant comments were made by Patient groups.

EAHP Members



Average score: 2.9

There was strong agreement with this statement. Comments received were:-

“Do you think the statement should be amended to specify medical doctors and nurses? Do you think that would then limit it, as it may be important for dieticians, physiotherapists and other allied healthcare professionals to be aware of the pharmacy service?”

“I would add that also hospital pharmacists should teach on pharmacy and prescribing courses (not only advise) at least in undergraduate studies.”

“I think that in this statement we should set the minimum for hospital pharmacy studies in undergraduate curricula all over Europe. It reads on a statement but not in hospital pharmacists explanation text now. Hospital pharmacists should also have multidisciplinary studies in undergraduate curricula.”

“Competency in what is essential? Hospital pharmacy, multidisciplinary teamwork or what?”

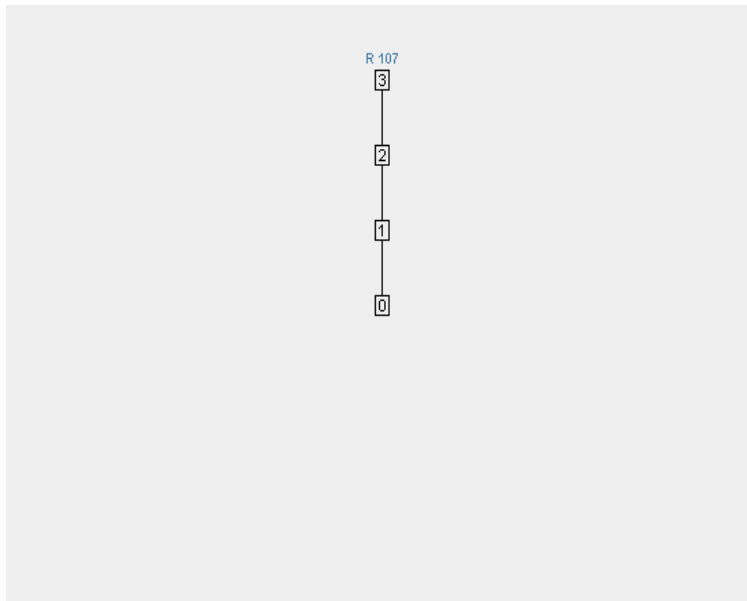
“For all pharmacists at least introduction to hospital pharmacy course is essential (even if you wouldn't going to work in hospital) to understand the medication process starting from hospital and ending in community care.”

“this should be achieved by extensive practice based training throughout the course and through inter-professional learning including direct patient care and physical examination skills at the patient bedside with advanced pharmacy practitioners and pharmacy consultants”

Conclusion: no amendment is required to the statement for the Delphi 2 process.

[Drafting note for moderator and EAHP: Is “promoted” the right tone, and could it be more specific? Would **The undergraduate curricula for all health professionals should include an introduction to hospital pharmacy practice work?** NM

Partner health organisations



Two comments were received:-

“As mentioned earlier, section Information on healthcare professionals, the nursing prescribing issue”

“To consult the Specialist Nurses Organisation about the Specialist Nurses title in some nations with authorisation for prescribing adding to the discussion and/or including in the statement.”

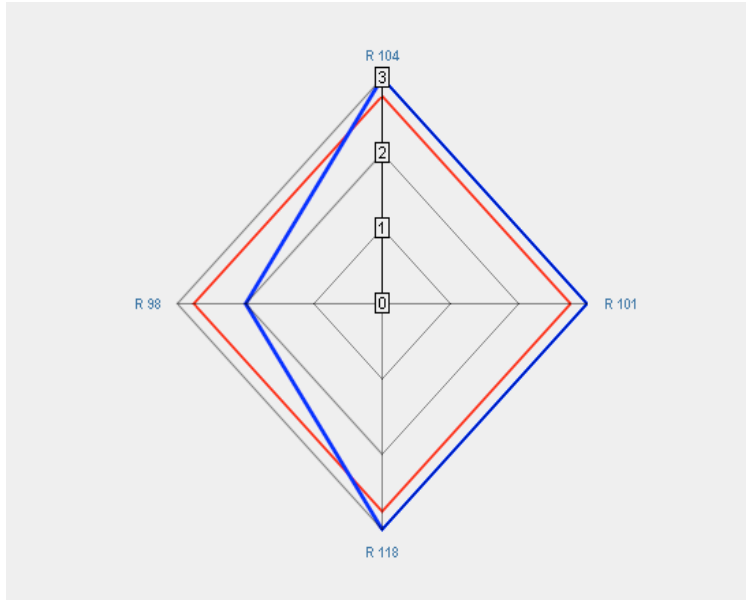
Conclusion: the issue of non-medical prescribers can be addressed in other statements and in implicit in this statement.

Action: no revisions to statement are required for the Delphi 2 process.

Undergraduate pharmacy curricula should include an introduction to hospital pharmacy practice. The role of hospital pharmacists should be promoted in the curricula of other health professionals.

6.2 Post graduate education in the hospital setting, with a final assessment of individual competency is essential to ensure that where pharmacists are providing hospital pharmacy services, patients benefit from the highest levels of expertise. (Statement 43).

Patient groups



Average score: 2.75

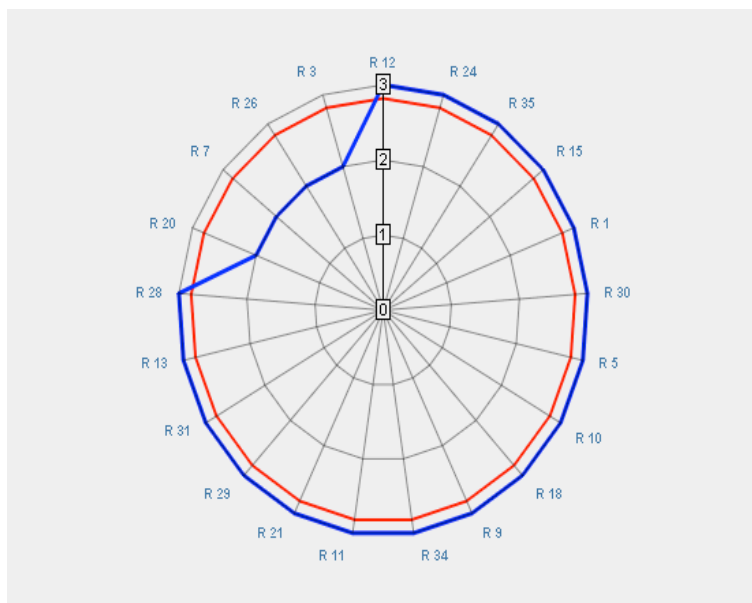
One comment was received.

“Not sure whether more and more education really makes for better practitioners in all health areas. Competencies can also be gained through practice.”

This statement covers the period of initial postgraduate education and training rather than lifelong learning, which should indeed be influenced by learning and reflection in the context of practice.

Conclusion: no revision required.

EAHP Members



Average score: 2.81

Comments received were:-

"A final assessment (examination) of the post graduate education is important in order to have a comparable level of training and recognition of qualifications in whole Europe"

"The final assessment (examination) should be comparable in whole Europe to ensure an equal level of training and recognition of qualifications."

"An optimal training with investment of qualified hospital pharmacists. I agree, and in our country this is regulated already by law"

"If a country is not able to provide an adequate hospital setting for this purpose, this could be done in another country. Common training framework will provide this opportunity in the future."

"It is imperative to harmonize the curricula of post graduate pharmacy education. Continuous professional education and development is also of high importance."

"Since hospital is a high risk environment continuous and weekly training and development is necessary. This is not covered in the statement"

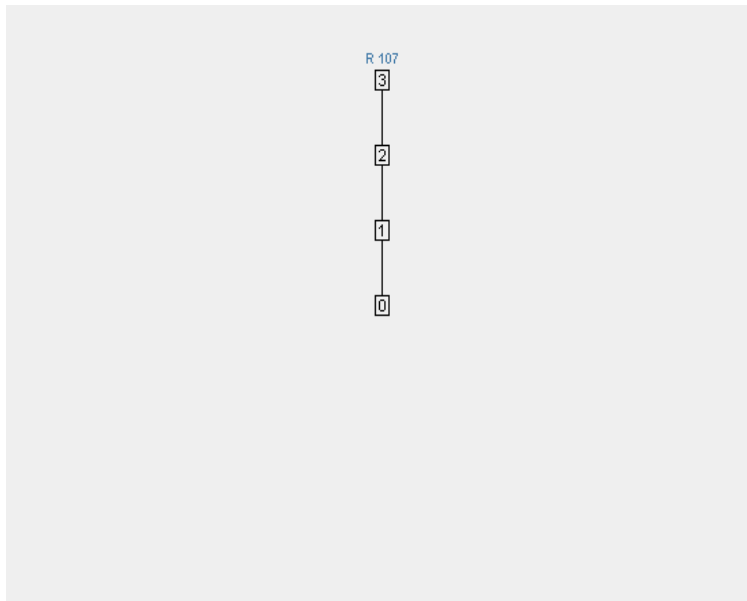
"I would take the lack of an EU level mutual recognition part away from healthcare professionals explanation text because it is not key content for that. Even without post graduate hospital pharmacy training other healthcare professionals can still trust that pharmacists are experts in medication. It is enough when EU level mutual recognition is in hospital pharmacists explanation text."

"similar to undergraduate practice"

Conclusion: the issue of European – wide standardisation is addressed in the next statement. No revision is required to the statement for Delphi 2.

Postgraduate education in the hospital setting, with a final assessment of individual competency is essential to ensure that where pharmacists are providing hospital pharmacy services, patients benefit from the highest levels of expertise.

Partner health organisations



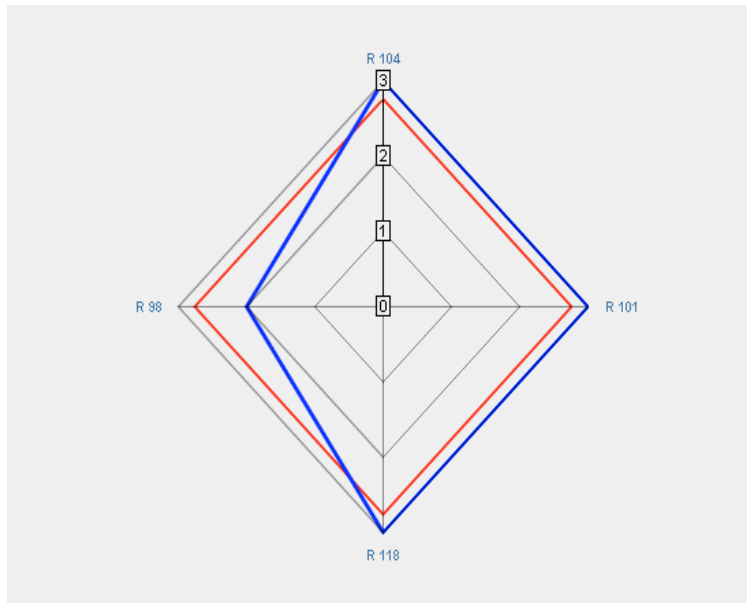
No significant comments were made by Partner Health organisations.

Action: No revision is required to the statement for Delphi 2.

Post graduate education in the hospital setting, with a final assessment of individual competency is essential to ensure that where pharmacists are providing hospital pharmacy services, patients benefit from the highest levels of expertise.

6.3 Hospitals should use a European accepted competency framework to assess individual human resource training needs and performance of hospital pharmacists. This should be defined and used regularly to assess all candidates. (Statement 44).

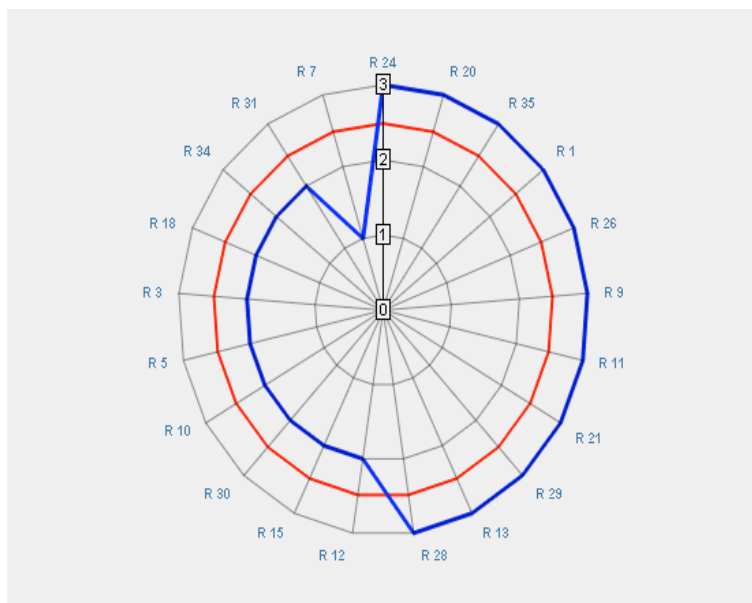
Patient groups



Average score: 2.75

No significant comments were received from Patient groups.

EAHP Members



Average score: 2.48

"Hospital must use European accepted competency framework, but the government must be aware for this too."

"candidates sound odd in a way" "why not just prospective or future Hospital pharmacists?"

"European accepted competency framework needs to take into account different settings within European countries for individual human resource training needs and performance of hospital pharmacists assessment."

"It is really important that EU-wide harmonization preceded the local implementations. Would not make them less difficult though."

"'....European accepted competency framework...' should be amended to '....European accepted minimum competency framework....'. Some countries have established a specialist education in hospital pharmacy that probably will remain more comprehensive than what will be recommended in a common European competency framework."

"It is an important item, but it also has to be considered in agreement with the national education system."

"provided it meets the needs of all countries"

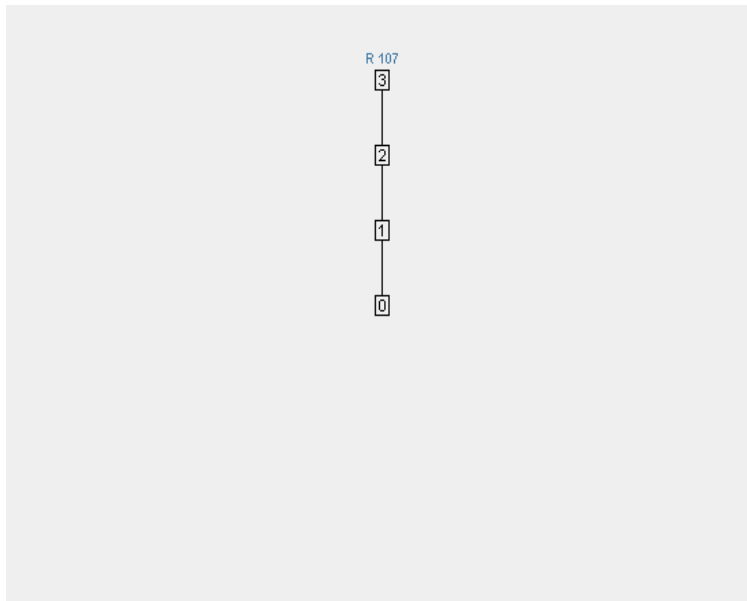
"I agree, but to make this in practice, it will take a lot of work; Universities from all European countries must give the same education program to have hospital pharmacist, all over Europe that have the same capabilities"

"Each national healthcare system is unique and therefore a competency framework should be developed to national prerequisites. Certain common criteria could of ours be accepted on a European level or even better established by the WHO, ie establishing certain necessary core competencies"

Conclusion: the comments and general level of agreement with the statement seem to indicate some concerns about the feasibility of a European-wide competency framework and assessment for hospital pharmacists after initial training and when they are established in their career paths. In order to hopefully improve the consensus, suggest revision for Delphi 2 process to:-

A European-wide competency framework to regularly assess performance and training needs of hospital pharmacists should be developed and implemented. This should contain core minimum competencies which would be applicable to all hospital pharmacists; given the heterogeneity of hospital pharmacy practice in different countries, additional national competency frameworks should be considered.

Partner health organisations



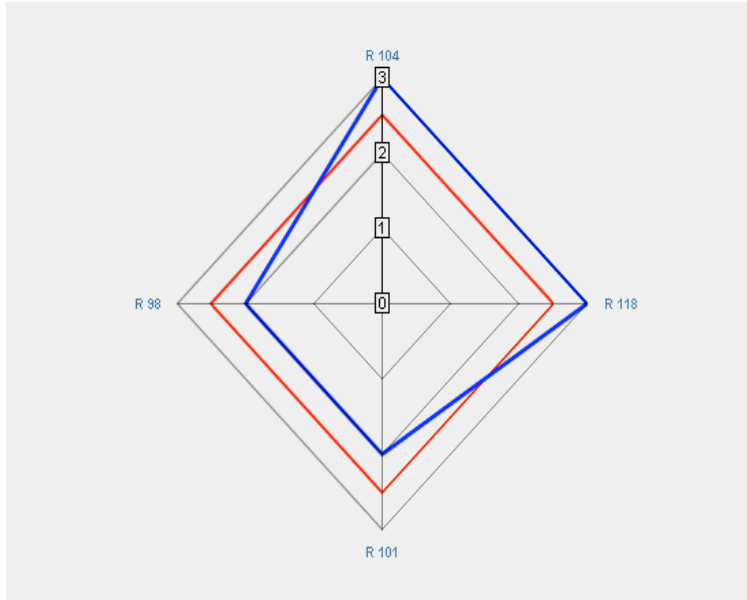
No comments were made by Partner Health organisations.

Action: revision for the Delphi 2 process to:-

A European-wide competency framework to regularly assess performance and training needs of hospital pharmacists should be developed and implemented. This should contain core minimum competencies which would be applicable to all hospital pharmacists; given the heterogeneity of hospital pharmacy practice in different countries, additional national competency frameworks should be developed and implemented.

6.4 The training of all other staff involved in medication use processes should be nationally formalised, harmonised, including the details of defined competencies for the attainment of defined scope of practice. (Statement 45).

Patient groups



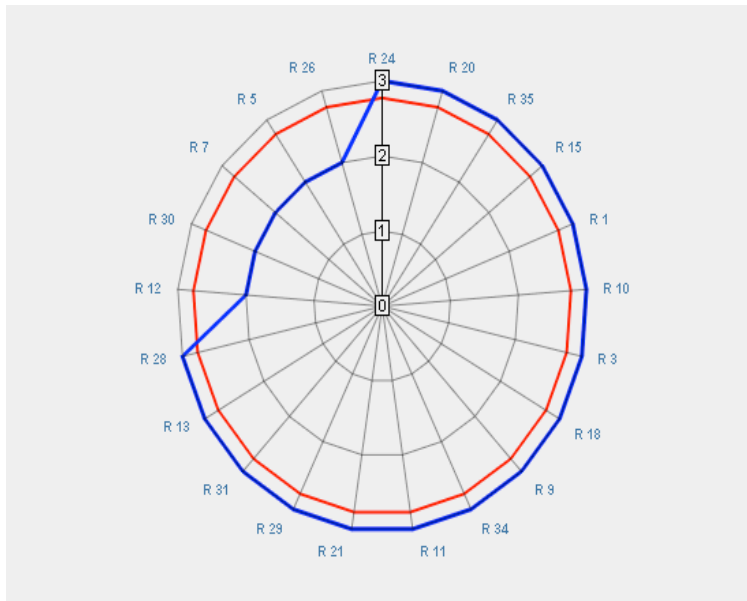
Average score: 2.5

One significant comment was received.

"I'd add the European level so to link this statement to the previous one(s)"

Conclusion: mirroring the wording of the previous statement should be considered.

EAHP Members



Average score: 2.76

The following comments were received:-

"Very important. Very often the other staff want to be pharmacists"

"Formally recognized specialization for pharmacy technicians would also be recommended (ie. oncology, unit dose dispensing, etc)."

"Certain necessary core competencies should be established on a national level"

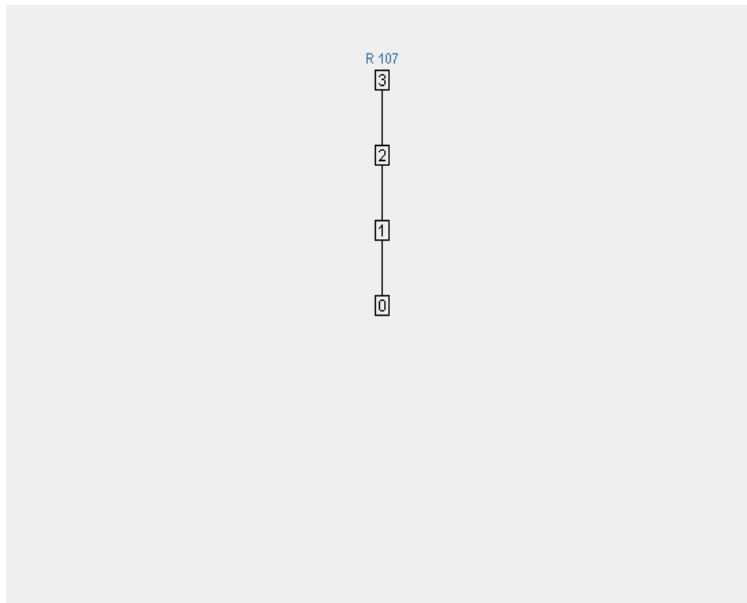
"As this is not the main task of a hospital pharmacist, we would prefer: "The coaching and training of all other staff involved in medication use processes should be considered in a national level, including the details of defined competencies for the attainment of defined scope of practice."

"From my perspective "other staff involved in medication use process" includes also e.g. nurses, but I think the focus in this statement is on technicians and assistants like it is said in explanation texts. Could we speak about technicians and assistants also on general statement text?"

Conclusion: whilst there is better agreement with this statement than the previous associated statement, a rewording so that the two statements mirror each other is proposed:-

A European-wide competency framework and training programme to support all other staff involved in medication use processes should be developed and implemented.

Partner health organisations



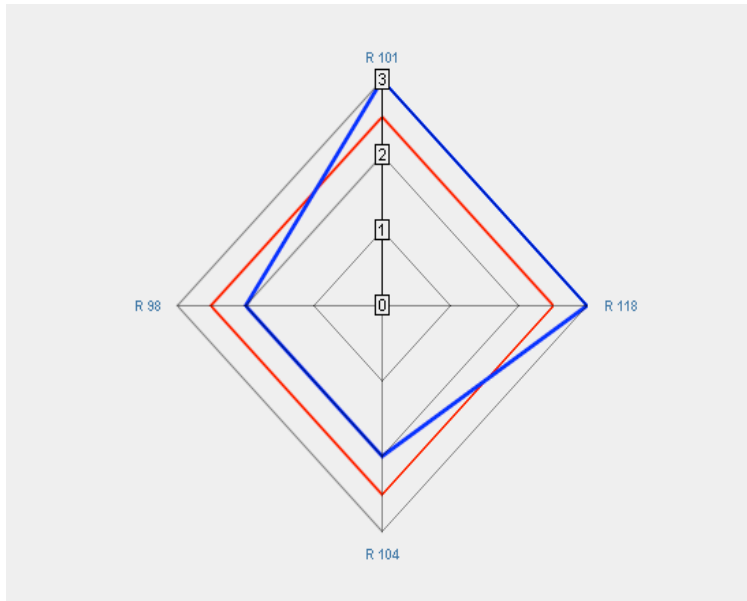
No comments were received from Partner Health organisations.

Action: the following revised statement is proposed for the Delphi 2 process.

A European-wide competency framework and training programme to support all other staff involved in medication use processes should be developed and implemented.

6.5 Hospital pharmacists should provide orientation and education to healthcare providers regarding best practices for medicine use for patients. (Statement 46).

Patient groups

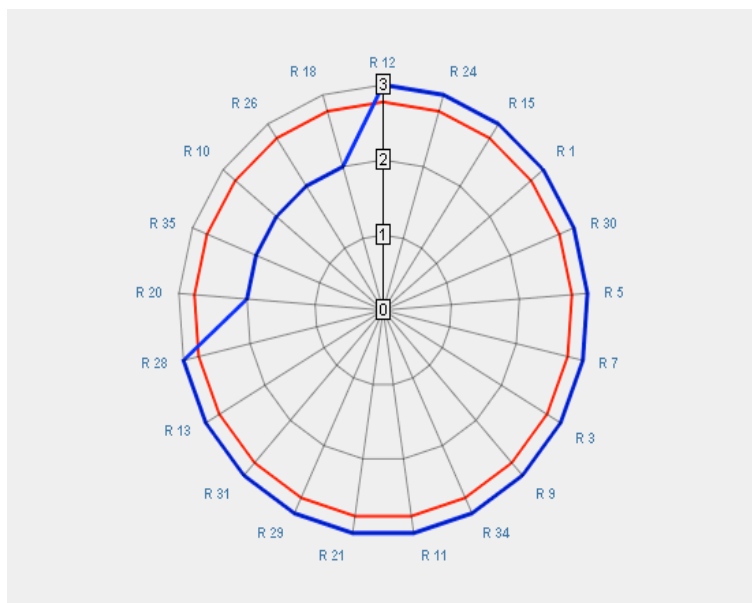


Average score: 2.5

One comment was received from patient groups:-

"More information exchange would be good, but this should be a collaborative effort."

EAHP Members



Average score: 2.76

The following comments were made:-

“including pharmacists as healthcare providers”

“These activities should be supported by respective faculty of pharmacy.”

“should be involved at least “

“does this mean educating patients. if so, then this statement is similar to statement 29 “

“what is meant by orientation - this sound vague; guidance as an alternative?”

“My understanding is that this means educating other healthcare professionals about medicines use. Do you think this is confusing? If we removed the words 'for patients' would that help make it clearer? Regarding 'orientation', is 'guidance' better or would 'advice' be better still?”

“advice is fine with me. to me this is confusing. Does this mean that pharmacists should educate health care professionals in order that they are able to educate patients? the erasure of “for patients” would make it clearer in my opinion”

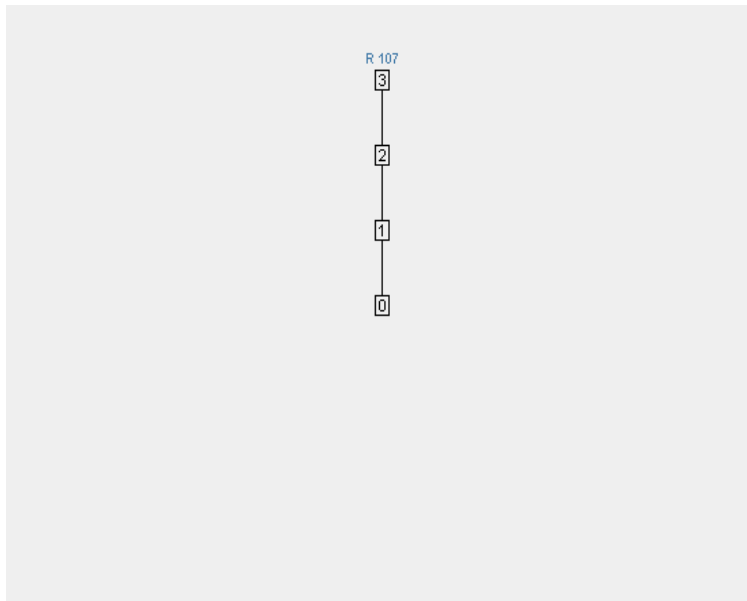
“In healthcare professionals explanation text last sentence (“This should include prescribers...”). Is there need for that because I think the same things have already been said in previous sentences?”

“Why in hospital pharmacists explanation text only education on the administration of hazardous drugs and pharmacovigilance are mentioned? There is so much also other things that hospital pharmacists can teach (e.g. medication safety in general, drug related problems, medication information...)”

Conclusion: minor wording changes could potentially improve further the consensus on this statement. The following is proposed for Delphi 2:-

Hospital pharmacists should provide orientation and education to other healthcare providers on best practices for medicine use.

Partner health organisations



Average score:

The following comments were received:-

"As mentioned earlier, adding to health care professionals / information"

"For patient safety doctors can benefit from continually updated education..."

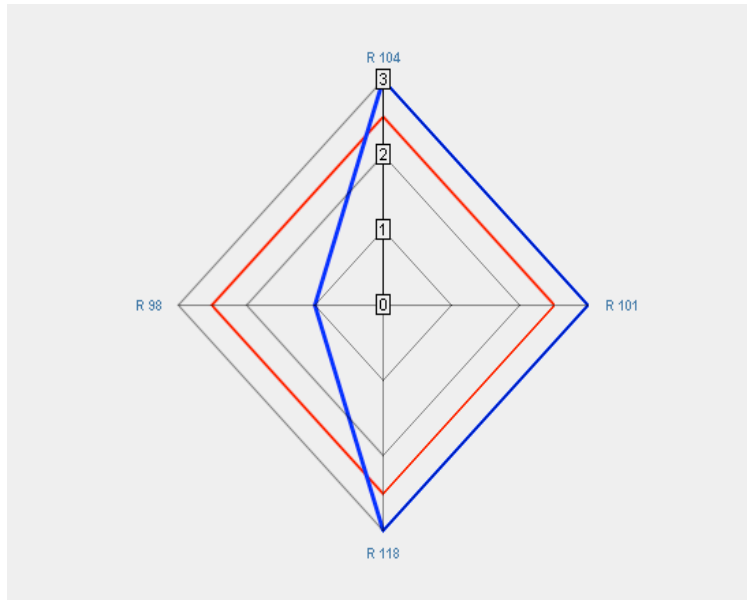
"To consider the role of the 'special trained specialist nurses and qualified and authorised in the education role of general trained nurses."

Action: the following revised wording is proposed for Delphi 2:-

Hospital pharmacists should provide orientation and education to other healthcare providers on best practices for medicine use.

6.6 Hospital pharmacists should actively engage in research into improving and creating new methods and systems to optimise the use of medicines for the benefits of patients. Research methods should be part of postgraduate training programmes for hospital pharmacists. (Statement 47).

Patient groups

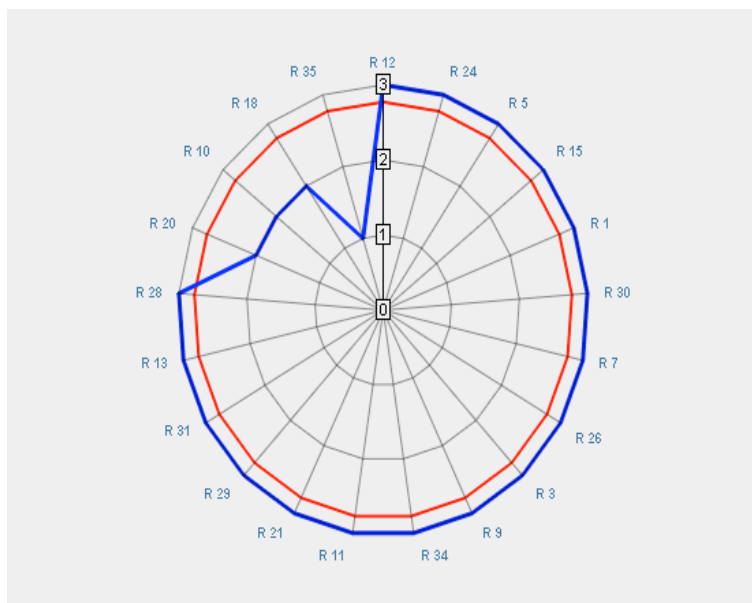


Average score: 2.5

The following comment was made:-

"Not sure if this is necessarily a core task of hospital pharmacists".

EAHP Members



Average score: 2.76

The following comments were made:-

"Academic positions in hospital pharmacy should be developed in the universities - Continuing education courses on research in hospital pharmacy should be provided to all hospital pharmacists - National congresses should encourage the presentation of research projects as posters/oral communication"

'Hospital pharmacists should actively engage in research into improving and creating new methods and systems to optimise the use of medicines for the benefits of patients. Academic positions in hospital pharmacy should be developed in the universities and research methods should be part of postgraduate training programmes for hospital pharmacists.'

this may involve discontinuing therapy with the informed consent of patients

Hospital pharmacists are very good and in fact obliged partners in the research of improving the medication use systems new services

Hard to achieve in a small country where pharmacists cannot be sure that they will work their whole life in the hospital. They have to be flexible: able to work in hospitals, industry etc

*I am missing a statement on **hospital pharmacy practice research** which is vital for our profession and creating the evidence base that supports our services. It is not only about doing research, but also about publishing. This is intertwined.*

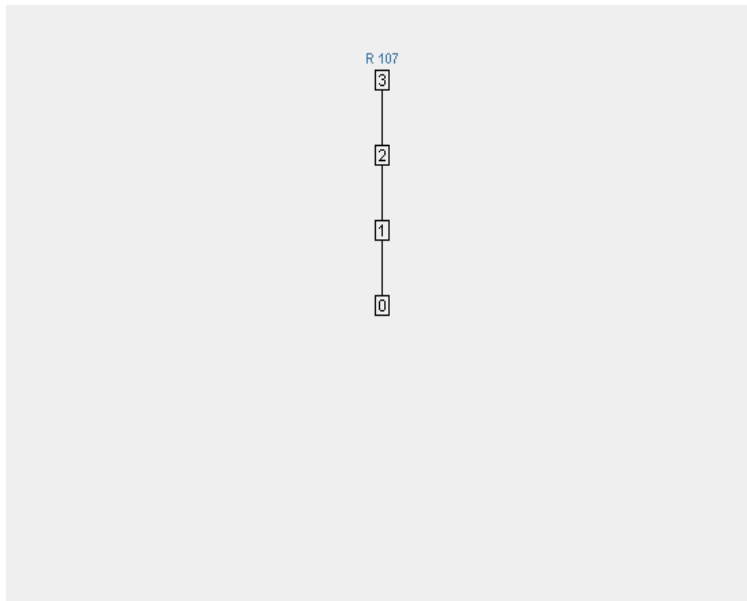
I would suggest just addingshould actively engage in Hospital pharmacy practice Research intofor the benefits of patients, and publish their results. This term is broad enough to capture all types of Research done by pharmacists or in the pharmacy.

Conclusion: minor revisions may improve further the consensus on this statement. The following is proposed for the Delpi 2 process:-

Hospital pharmacists should actively engage in hospital pharmacy practice research which describes improving existing and creating new methods and systems to optimise the use of medicines for the benefit of patients. Research methods should be part of postgraduate training programmes for hospital pharmacists.

[Note for moderators and EAHP: is there a point that needs making about funding for hospital pharmacy practice research and academic positions?]

Partner health organisations



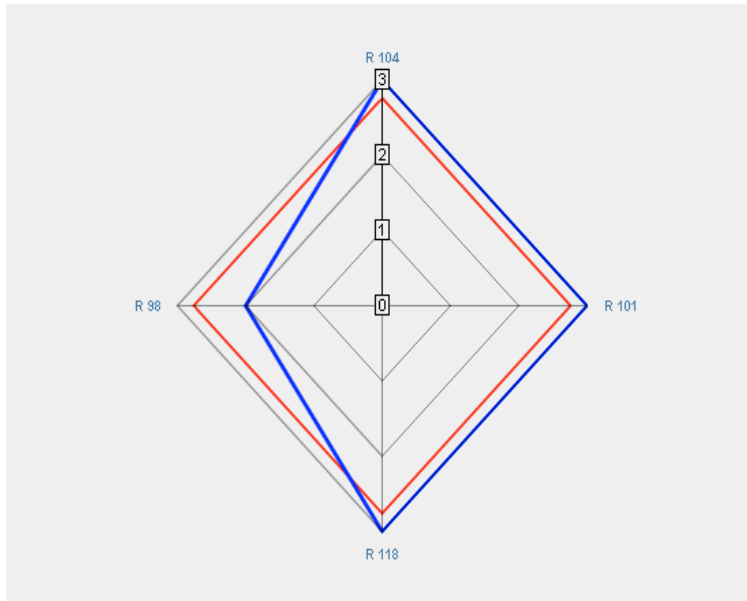
No significant comments were made by Partner Health organisations.

Action: the following is proposed for the Delphi 2 process:-

Hospital pharmacists should actively engage in hospital pharmacy practice research which describes improving existing and creating new methods and systems to optimise the use of medicines for the benefit of patients. Research methods should be part of postgraduate training programmes for hospital pharmacists.

6.7 Hospital pharmacists should be actively involved in the management and medicine use processes relating to clinical trials. (Statement 48).

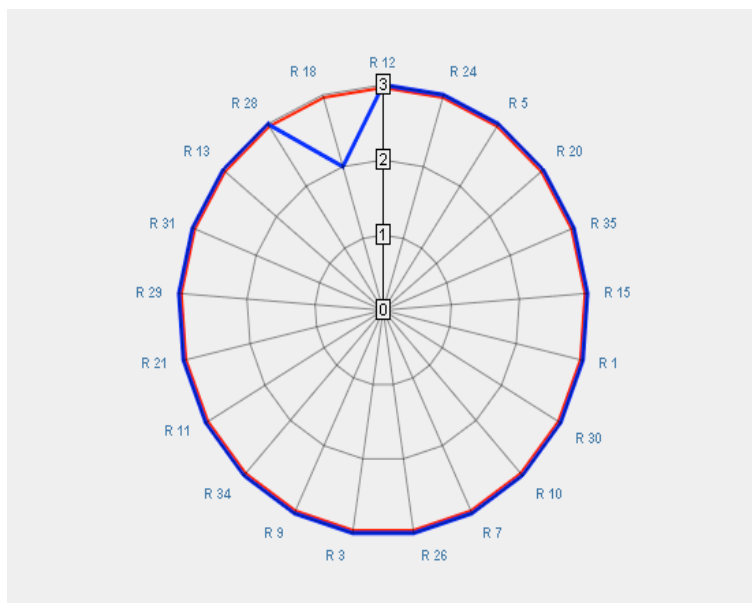
Patient groups



Average score: 2.75

No significant comments were made by patient groups.

EAHP Members



Average score: 2.95

The following comments were made:-

"No comment because our legislative do not include pharmacists in clinical trials"

"Regulations should force any medication for clinical trials to be managed by the pharmacy, in all countries2"

"no additional comment in our country clinical trial medication must be managed by hospital pharmacists, even with more regulations than with other medicines"

*"Hospital pharmacists **MUST** be involved in the management and medicine use processes relating to clinical trials. This should be compulsory for each trial in each institution."*

"I know that the word must is too strong, but considering the fact that in some countries clinical trials are conducted without hospital pharmacists active involvement, "must" may be appropriate for this statement."

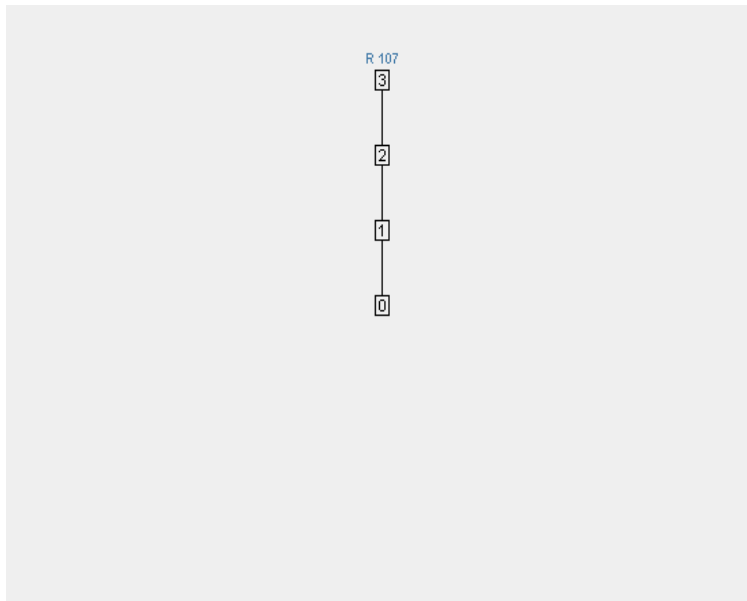
"Legislative implementation of this statement on a national level should be made mandatory."

"Currently hard to achieve as physicians do not want share money"

Conclusion: despite the excellent consensus, changing "should" to "must" is proposed for this statement for the Delphi 2 process:-

Hospital pharmacists must be actively involved in the management and medicine use processes relating to clinical trials.

Partner health organisations



No significant comments were made by partner organisations.

Action: the following statement is proposed for the Delphi 2 process:-

Hospital pharmacists must be actively involved in the management and medicine use processes relating to clinical trials.