The European Statements of Hospital Pharmacy: achieving consensus using Delphi and World Café methodologies

Neal Maskrey,[1] Jonathan Underhill[2]

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[1]School of Pharmacy, Keele University, Newcastle-under-Lyme, Staffordshire, UK
[2]Centre for Medicines Optimisation, Keele University, Newcastle-under-Lyme, Staffordshire, UK

Correspondence to
Professor Neal Maskrey, School of Pharmacy, Keele University, Newcastle-under-Lyme, Staffordshire ST5 5BG, UK; Neal.Maskrey@nice.org.uk

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ABSTRACT

In developing the European Statements of Hospital Pharmacy, a method was required that afforded participants the opportunity to contribute to the wording of the statements, and provided a way to measure the level of agreement. Given the diversity of hospital pharmacy service delivery across Europe, it was envisaged that an explicit, objective and inclusive approach was required to achieve consensus. A two stage approach was therefore designed: a Delphi process followed by a World Café workshop. The sequential use of these two processes in a highly complex context with a requirement for significant international collaboration was highly successful as a consensus building approach. We recommend the sequential use of these two techniques for achieving consensus in similarly complex decision making processes.

INTRODUCTION

Quantitative methods such as meta-analysis have been developed to improve the statistical agreement of data and improve its validity. This is more difficult when conducting qualitative research or when seeking to produce consensus statements. Consensus methods can help deal with conflicting evidence or views by determining the extent of agreement about a given issue. They can address some of the disadvantages normally found with decision making in groups or committees, which runs the risk of bias due to domination by one or more powerful individuals, or by coalitions representing vested interests. In open committees, individuals are often not ready to retract long-held and publicly stated opinions, even when these have been proved to be false.[1]

In developing the European Statements of Hospital Pharmacy, a method was required that afforded participants the opportunity to contribute to the wording of the statements, and to provide a method to measure the level of agreement. Given the diversity of hospital pharmacy service delivery across Europe, it was envisaged that an explicit, objective and inclusive approach was required to achieve consensus. A two stage approach was therefore designed: a Delphi process followed by a World Café workshop.

STAGE 1: THE DELPHI PROCESS

What is the Delphi method?

The term Delphi originates from Greek mythology, Delphi being the residence of a wise oracle—'the Delphic oracle'. The Delphi method or process was developed in the early 1950s by Olaf Helmer and Norman Dalkey of the RAND Corporation. It was developed to solicit the views of experts related to national defence and other controversial socio-political areas of discourse. The original intent was to enhance strategic planning by improving the accuracy of predictions concerning future trends and priorities. While largely discounted for its original purpose, it remains a useful technique in improving decision making by enhancing consensus or agreement among experts or stakeholders.[2]

Evidence shows that using the Delphi method enables a structured communication technique to maximise the benefits of group decision making while minimising the negative aspects of group dynamics such as 'groupthink'.[2]

How the process is applied

The general principles of the Delphi method involve[2]:

- Anonymised collation of responses from participants
- Oversight of responses by an anonymous facilitator
- Analysis of responses and objective measurement of agreement
- Participants being asked to explain a problem or predict a future state of affairs
- Facilitators controlling interactions among participants by processing the information and filtering out irrelevant content
- Replies being gathered, summarised, and then fed back to all group members
- Iteration of the process until the responses converge satisfactorily and an agreed level of consensus is achieved.

To initiate the process, an expert workshop was held where 48 initial statements were drafted, using as a base the 2008 International Pharmaceutical Federation (FIP) 'Basel' statements on hospital pharmacy practice.

These statements were categorised under six headings:

1. Introductory statements and governance
2. Selection, procurement and distribution
3. Production and compounding
4. Clinical services
5. Patient safety and quality assurance
6. Education and research.

The Synmind software and platform (http://www.synmind.com/) was utilised for an online, two round, Delphi process. An anonymous facilitator was assigned to each category. European Association of Hospital Pharmacists (EAHP) members together with representatives from patient and other healthcare professional groups were invited to read the draft

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statements and indicate their level of agreement on a scale of 0–3 (where 0 is strongly disagree and 3 is strongly agree). Participants were also asked to give a justification for their response in the free text boxes under each statement. Round 1 took place in November and December 2013. Statements were revised based on the results of that round and were subjected to further online discussion and voting in round 2 which took place in January and February 2014.

Key results from rounds 1 and 2 of the Delphi process

The level of agreement with the initial draft statements improved during both rounds of the Delphi process. Over the two rounds, the mean score for 25 statements improved by more than 0.1 and no statement had a score which fell by more than 0.1. Sixteen statements remained unchanged from round 1, while 22 statements were unchanged in round 2. During round 1, no statements were removed but one statement moved from section 3 to 4.

In round 2, three statements were amalgamated and section 3 was reordered with one further statement proposed for amalgamation to be discussed at the next stage of the process. Of the 45 revised statements, 33 had an overall score for agreement at the end of the Delphi process of more than 2.75.

Following the second round of the Delphi process, further refinements were made to the statements based on the outcomes of that second round. Those statements then proceeded to the second stage of consensus building—the World Café.

See online supplementary appendix 1 for details of the review of the statements during the Delphi process.

STAGE 2: THE WORLD CAFÉ METHOD

The World Café process[3] was devised serendipitously in 1995 by a small group of business and academic leaders in Mill Valley, California. During a group discussion, the 24 participants spontaneously formed into small, intimate table conversations on the issues that had drawn them together. Recording the important points of agreement on makeshift paper tablecloths, they periodically switched tables so the insights and ideas that had real power might circulate, deepen and connect. A record of the important insights enabled them to discern the emerging patterns in their thinking, which then enriched subsequent rounds of conversation. This improvised process produced a collective intelligence that transformed the depth, scope and innovative quality of their collaboration.

The World Café process relies on a number of factors:

- *Set the context*: Participants must be clear on the purpose of the meeting in order to consider and choose the most important elements.
- *Create a hospitable space*: The environment in which the discussions take place must feel safe and inviting in order to stimulate creative thinking, speaking and listening.
- *Explore questions that matter*: Knowledge emerges in response to compelling questions, so facilitators should be prepared to ask questions that are relevant to the most pressing concerns of the group.
- *Encourage everyone's contribution*: Some participants may be reluctant to contribute while some will be overly keen. Finding the balance is a key component of the facilitator's role.
- *Connect diverse perspectives*: The opportunity to move between tables and meet new people thereby linking the conversations to ever-widening circles of thought is one of the distinguishing characteristics of the World Café. As participants carry key ideas or themes to new tables, they exchange perspectives, greatly enriching the possibility for surprising new insights.
- *Listening for patterns and insights*: The quality of the listening is perhaps the most important factor determining the success of a Café.
- *Share collective discoveries*: The last phase of the World Café is the 'harvest' where the collective discussions held throughout the day are discussed in a smaller group to capture the key elements and reach consensus.

In applying these principles at the EAHP Summit in Brussels, six 'tables' were created, each devoted to one set of statements. Two facilitators were assigned to each table, plus a note taker. Participants at the summit were each given a unique timetable for the day that meant each of them spent time at each table for 40 min of facilitated discussion on the set of statements for that table. Individuals then moved to a new table with a different group of participants. This enabled each participant to discuss each set of statements while not allowing 'cliques' to form or 'groupthink' to develop.

Within each group, the set of statements was explored in turn and the facilitators recorded key points of agreement or disagreement. Agreed changes to the statements were written on the tablecloths to inform the 'Harvest' discussions in producing revised statements at the end of the World Café. These revised statements were then subject to a vote on day 2 of the summit. See page 267 for details of the voting process.

Key changes to the statements from the World Café workshop

Online supplementary appendix 1 gives details of how the statements evolved throughout the Delphi and World Café stages to produce the draft statements on which participants voted on day 2 of the summit.

Most of the discussions during the World Café involved simplifying the wording of some statements, and improving the flow within groups of statements. This often involved reordering statements within each section so that the important statements were listed first to give them greater emphasis. There was also general agreement around the use of the words 'must' where participants felt this was a minimum requirement and 'should' where it was recognised that adopting the statement may be currently be aspirational for some countries. A strongly emergent theme, continuing a trend from the Delphi process, was the importance of emphasising collaboration with other healthcare professionals and the role for pharmacists in actively engaging in clinical decision making as part of a multidisciplinary healthcare team, and with patients.

Section 3 on production and compounding was subject to the largest iterative change, continuing another trend in the Delphi process. This was a section which was not included in the 2008 FIP statements, and perhaps the volume of discussion on this section was a reflection of having to devise original statements for the whole section.

The order of the statements in Section 3 was changed to reflect the sequence of how participants felt production and compounding should take place. This finally flowed from encouraging use of commercially available products where available, to outsourcing under the responsibility of a pharmacist, then undertaking risk assessment where production or compounding was deemed appropriate, and finally ensuring quality assurance and hazard prevention measures were in place.

The end product of the Delphi and World Café processes was a revised set of 44 statements that were presented for the final voting stage on day 2 of the Summit.

DISCUSSION

We are unable to find other descriptions of the sequential use of a Delphi process followed by a World Café workshop as a consensus building approach in healthcare. Both processes delivered increasing consensus, and they worked synergistically. No unfavourable comments were made about the Synmind platform utility by participants, and it was favourably received by the Delphi facilitators. The World Café process was nothing less than a delight, with productive and considered input from all participants who were fully engaged throughout the day. Harvesting the end product at the end of the day took several hours, a consideration for others who may consider emulating this approach.

In ideal circumstances the Delphi facilitators would have received input from all participants early in each of the rounds. This would have enabled more discussion between participants and facilitators to explain the positions and views expressed, and between the participants themselves. It is, however, entirely understandable that a number of busy healthcare professionals, often in senior positions within their organisations, were only able to take part close to the end of a Delphi round.

CONCLUSION

The sequential use of a Delphi process followed by a World Café workshop in a highly complex context with a requirement for significant international collaboration was very successful as a consensus building approach. We recommend the sequential use of these two techniques in achieving consensus in similarly complex decision making processes.

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Contributors NM moderated the two rounds of the Delphi process, leading the collation of comments and revisions of statements. JU facilitated one category of statements in the Delphi process and observed the remaining categories as they progressed through the Delphi process. JU suggested the synergistic use of the World Cafe workshop. NM led the team facilitating the World Cafe process, and JU facilitated one category of statements. JU wrote the first draft of this paper, which was then revised by NM. Both authors agreed on the final version of the paper.

Competing interests Both authors are employed part-time by the National Institute for Health and Care Excellence.

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3 http://www.theworldcafe.com/method.html

Section	Statement number	Delphi 1 Statement	Delphi 2 statement	Notes	Final statement number	Final agreed statement
1.1	1	The overarching goal of hospital pharmacists is to optimise patient outcomes through the judicious, safe, efficacious, appropriate, and cost effective use of medicines.	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.	Change reflects universality of multidisciplinary team as the basis of care provision.	1	The overarching goal of the hospital pharmacy service is to optimise patient outcomes through working collaboratively within multidisciplinary teams in order to achieve the responsible use of medicines across all settings.
1.2	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.	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.	Change to acknowledge "best available evidence", together with minor wording changes to increase clarity of phrasing.	2	At a European level, 'Good Hospital Pharmacy Practice' guidelines based on the best available evidence should be developed and implemented. These guidelines will include corresponding human resources and training requirements and assist national efforts to define recognised standards across the scope and levels of hospital pharmacy services.
1.3	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	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	Reworded to reflect a balance between experience and explicit training and demonstration of competence.	3	Health systems have limited resources and these should be used responsibly to optimise outcomes for patients. Hospital pharmacists should develop, in collaboration with other stakeholders, criteria and measurements to enable the prioritisation of hospital pharmacy activities.

		Hospital.	**hospital pharmacy services, including those without a pharmacy in the hospital.**			
1.4	**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**	**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.**	**Wording now reflects the option of a wider range of stakeholders, and wording separates the development of HR plans from their implementation.**	**4**	**All hospitals should have access to a hospital pharmacist who has overall responsibility for the safe, effective and optimal use of medicines. Health authorities should ensure that each hospital pharmacy is supervised by a pharmacist with appropriate working experience in the hospital setting, and explicit demonstration of competence in hospital pharmacy.**
1.5	**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**	**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-**	**Rewording clarifies the role of hospital pharmacists in relation to Drug and Therapeutic Committees.**	**5**	**Hospital pharmacists should work with all relevant stakeholders to develop hospital pharmacy human resource plans covering the breadth of hospital pharmacy practice. 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.**

			counterfeit medicines strategies.			
1.6	**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.**	**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.**	**No changes.**	**6**	**Hospital pharmacists should take the lead in coordinating the activities of multi-disciplinary, organisation-wide Drug & Therapeutics Committees or equivalent. They should have appropriate representation as full members of these Committees which should oversee and improve all medicines management policies.**
1.7	**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.**	**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.**	**Rewording strengthens and clarifies the role of stakeholders.**	**7**	**Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes. This will 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.**
2.1	**8**	**Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital**	**Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital**	**Transparency added to wording.**	**8**	**Hospital pharmacists should be involved in the complex process of procurement of medicines. They should ensure transparent procurement processes are in place in line with best practice and national legislation, and based on the**

		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.	**pharmacists should establish transparent procurement processes based on principles of safety and quality of medicines, in line with best practice and national legislation.**			**principles of safety, quality and efficacy of medicines.**
2.2	9	**Hospital pharmacists should have responsibility regarding the management of medicine use processes and medicine related technologies.**	**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.**	**Revised wording represents the responsibility is shared with other health care professionals.**	9	**Hospital pharmacists should take the lead in developing, monitoring, reviewing and improving medicine use processes and the use of medicine related technologies. Responsibility for using these processes may rest with other health care professionals and may vary according to the medicine, the medicine related technology, the health care setting and the multidisciplinary team delivering care.**
2.3	**10**	**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.**	**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**	**Revised wording includes patient outcomes and pharmacoeconomic evaluations.**	**10**	**Hospital pharmacists should coordinate the development, maintenance and use of a medicines formulary system, which may be local, regional and/or national. The medicine formulary system should be linked to guidelines, protocols and treatment pathways based on the best available evidence including patient outcomes and pharmacoeconomic evaluations where these are available.**

			are available.			
2.4	**11**	**Procurement must be according to the medicine formulary and informed by the formulary selection 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.**	**Off-formulary procurement included in revised wording.**	**11**	**Procurement should 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	**12**	**Each hospital pharmacy should have contingency plans for shortages and purchases for medicines and all products under its responsibility.**	**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.**	**Collaboration with others included in revised working.**	**12**	**Each hospital pharmacy should have contingency plans for shortages of medicines that it procures.**
2.6	**13**	**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.**	**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**	**No changes.**	**13**	**Hospital pharmacies should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, distribution and disposal conditions for all medicines, including investigational medicines.**
2.7	**14**	**Hospital pharmacists should support the**	**Unless specifically precluded by national**	**Caveat added to statement concerning national regulations**	**14**	**Hospital pharmacists should be involved in the development of policies regarding the use of**

		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.	**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.**	**precluding the use of medicines brought into hospital by patients.**		**medicines brought into the hospital by patients.**
3.1.	**15**	**Medicines not commercially available for special groups of patients that require compounding or production should be prepared by a hospital pharmacy.**	**Medicines not commercially available that require compounding or production should be prepared by a hospital pharmacy.**	**Simplification of wording.**	**15**	**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 the rationale for this decision with the relevant stakeholders.**
3.2	**16**	**Hospital pharmacists should appropriately develop pharmacy-managed injectables using aseptic technique.**	**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.**	**Clarification and rephrasing requirement indicated by Delphi 1 comments**	**16**	**Medicines that require manufacture or compounding must be produced by a hospital pharmacy, or outsourced under the responsibility of the hospital pharmacist.**
3.3	**17**	**When reconstitution takes place in the ward, a**	**When reconstitution takes place in the ward, a**	**No significant change.**	**17**	**Before making a pharmacy preparation, the hospital pharmacist must undertake a risk**

		hospital pharmacist should approve written procedures and ensure that the staff involved in reconstitution is appropriately trained.	**hospital pharmacist should approve written procedures and ensure that the staff involved in reconstitution are appropriately trained.**			**assessment to determine the best practice quality requirements. These must consider premises, equipment, pharmaceutical knowledge and labelling.**
3.4	**18**	**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.**	**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.**	**No significant change.**	**18**	**Hospital pharmacists must ensure that an appropriate system for quality control, quality assurance and traceability is in place for pharmacy prepared and compounded medicines.**
3.5	**19**	**Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards.**	**Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards.**	**No change.**	**19**	**Hazardous medicines should be prepared under appropriate conditions to minimise the risk of contaminating the product and exposing hospital personnel, patients and the environment to harm.**
3.6	**20**	**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**	**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.**	**Delphi 1 comments indicated revision to reflect a dialogue with colleagues as opposed to a refusal.**	**20**	**When the reconstitution or mixing of medicines takes place in a patient care area, a hospital pharmacist should approve written procedures that ensure staff involved in these procedures are appropriately trained.**

		and other healthcare professionals.				
3.7	**21**	**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.**	**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.**	**Minor wording change.**		
3.8	**22**	**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.**	**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.**	**Minor wording change.**		
3.9	**23**	**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.**	**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.**	**Minor wording change; should be moved to section 4, probably after 4.2 or 4.3.**		

4.1	**24**	**Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients outcomes.**	**Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients' outcomes**	**No significant change.**	**21**	**Hospital pharmacists should be involved in all patient care settings to prospectively influence collaborative, multidisciplinary therapeutic decision-making; they should play a full part in decision making including advising, implementing and monitoring medication changes in full partnership with patients, carers and other health care professionals.**
4.2	**25**	**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.**	**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.**	**Rephrased to reflect Delphi 1 comments to include "full part in decision making in partnership with patients".**	**22**	**All prescriptions should be reviewed and validated as soon as possible by a hospital pharmacist. Whenever the clinical situation allows, this review should take place prior to the supply and administration of medicines.**
4.3	**26**	**All prescriptions should be reviewed and validated by a hospital pharmacist prior to dispensing and administration of medication**	**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.**	**Caveats added to reflect clinical realities following comments from Delphi 1.**	**23**	**Hospital pharmacists should have access to the patients' health record. Their clinical interventions should be documented in the patients' health record and analysed to inform quality improvement interventions.**
4.4	**27**	**Pharmacists' clinical interventions should be documented in the patients' health record.**	**Pharmacists' clinical interventions should be documented in the patients' health record**	**No changes.**	**24**	**All the medicines used by patients should be entered on the patient's medical record and reconciled by the hospital pharmacist on admission. Hospital pharmacists should assess the appropriateness of all patients' medicines, including herbal and dietary supplements.**

4.5	**28**	**Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings.**	**Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings.**	**No changes.**	**25**	**Hospital pharmacists should promote seamless care by contributing to transfer of information about medicines whenever patients move between and within healthcare settings.**
4.6	**29**	**Hospital pharmacists should ensure that patients are educated on the appropriate use of their medicines**	**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.**	**Some revision of the statement was 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.**	**26**	**Hospital pharmacists, as an integral part of all patient care teams, should ensure that patients and carers are offered information about their clinical management options, and especially about the use of their medicines, in terms they can understand.**
4.7	**30**	**Pharmacists should inform and advise on and oversee the use of medicines outside of their marketing authorisation (off label use).**	**Pharmacists should inform and advise on the use of medicines outside of their marketing authorisation (off label use).**	**"Oversee" considered inappropriate since prescribing responsibility rests with the prescriber for off-label prescribing.**	**27**	**Hospital pharmacists should inform, educate and advise patients, carers and other health care professionals when medicines are used outside of their marketing authorisation.**
4.8					**28**	**Clinical pharmacy services should continuously evolve to optimise patients' outcomes.**
5.1	**31**	**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.**	**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.**	**No changes.**	**29**	**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.**
5.2	**32**	**Hospital medication practices should be**	**Hospitals should seek review of their medication**	**Clarification of wording.**	**30**	**Hospital pharmacists should ensure the development of appropriate quality assurance**

		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	**practices by an external quality assessment accreditation programme. Hospitals should act on reports as appropriate to improve the quality and safety of their practices.**			**strategies for medicines use processes to detect errors and identify priorities for improvement.**
5.3	**33**	**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**	**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.**	**MERS added in following Delphi 1 comments.**	**31**	**Hospital pharmacists should ensure their hospitals seek review of their medicines use processes by an external quality assessment accreditation programme, and act on reports to improve the quality and safety of these processes.**
5.4	**34**	**Hospital pharmacists should decrease the risk of medication errors by implementing evidence-based systems or technologies systems**	**Hospital pharmacists should help to decrease the risk of medication errors by disseminating evidence-based approaches to error reduction including computerised decision support.**	**Rewording to reflect the required multi-dimensional approach to reducing medication errors.**	**32**	**Hospital pharmacists should ensure the reporting of adverse drug reactions and medication errors to regional or national pharmacovigilance programmes or patient safety programmes.**
5.5	**35**	**The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated.**	**The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated**	**No changes.**	**33**	**Hospital pharmacists should help to decrease the risk of medication errors by disseminating evidence-based approaches to error reduction including computerised decision support.**

5.6	**36**	**High risk medicines should be identified and appropriate procedures implemented that assure checks prior to dispensing and administration.**	**High risk medicines should be identified and appropriate procedures implemented that assure checks prior to prescribing, dispensing and administration.**	**"Prescribing" added.**	**34**	**Hospital pharmacists should identify high risk medicines and ensure appropriate procedures are implemented in procurement, prescribing, preparing, dispensing, administration and monitoring processes to minimise risk.**
5.7	**37**	**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.**	**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.**	**No changes.**	**35**	**Hospital pharmacists should ensure that the medicines administration process is designed such that transcription steps between the original prescription and the medicines administration record are eliminated.**
5.8	**38**	**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**	**Hospital pharmacists should promote the reporting of adverse drug reactions to regional or national pharmacovigilance programmes.**	**Since the responsibility for analysising reports rests with regional or national authorities, the second sentence in this statement was revised.**	**36**	**Hospital pharmacists should ensure accurate recording of all allergy and other relevant medicine-related information in the patient's health record. This information should be accessible and evaluated prior to prescription and administration of medicines.**

		improve the quality and safety of medication practices				
5.9	**39**	**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.**	**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.**	**No changes. Requirement is to PROMOTE the recording, not to do it personally.**	**37**	**Hospital pharmacists should ensure that the information needed for safe medicines use, including both preparation and administration, is accessible at the point of care.**
5.10	**40**	**Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.**	**Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.**	**No changes.**	**38**	**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.**
5.11	**41**	**Hospital pharmacists should ensure that the information resources needed for safe medicines use, preparation and administration are accessible at the point of care**	**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.**	**No changes.**	**39**	**Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.**
6.1	**42**	**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**	**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.**	**No changes.**	**40**	**Undergraduate pharmacy curricula should include experience of hospital pharmacy practice. The role of all hospital healthcare practitioners, including hospital pharmacists, should be integrated into the curricula of other health professionals.**
6.2	**43**	**Post graduate education in**	**Post graduate education**	**No changes.**	**41**	**All those involved in medicines use processes**

		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.	**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.**			**must be able to demonstrate their competency in their roles. Hospital pharmacists should participate in the development of European-wide competency frameworks to ensure standards of best practtce are met.**
6.3	**44**	**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**	**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.**	**Comments from Delphi 1 indicated 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.**	**42**	**A European-wide framework for initial post graduate education and training in hospital pharmacy with an assessment of individual competence is essential. In addition, hospital pharmacists should engage in relevant educational opportunities at all stages of their career.**
6.4	**45**	**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.**	**A European-wide competency framework and training programme to support all other staff involved in medication use processes should be developed and implemented.**	**Rephrasing to match wording in statement 44.**	**43**	**Hospital pharmacists should actively engage in and publish research, particularly on hospital pharmacy practice. Research methods should be part of undergraduate and postgraduate training programmes for hospital pharmacists.**
6.5	**46**	**Hospital pharmacists should provide orientation and education to healthcare providers**	**Hospital pharmacists should provide orientation and education to other healthcare**	**Minor rewording changes.**	**44**	**Hospital pharmacists should be actively involved in clinical trials of medicines.**

		regarding best practices for medicine use for patients.	**providers on best practices for medicine use.**			
6.6	**47**	**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.**	**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.**	**Minor rewording to clarify.**		
6.7	**48**	**Hospital pharmacists should be actively involved in the management and medicine use processes relating to clinical trials.**	**Hospital pharmacists must be actively involved in the management and medicine use processes relating to clinical trials.**	**“Should” changed to “must”.**		