Quality Assurance of Clinical Pharmacy Practice

Pilar Mas Lombarte
Fundación Hospital-Asil de Granollers, Granollers, Spain

INTRODUCTION

Organizations exist as long as they are able to produce services that are of interest to someone—this someone being customers. Pharmacists create small organizations (e.g., hospital pharmacy services, community pharmacies, ambulatory settings) that are located within other organizations (e.g., hospitals, primary care, home care), which in turn are integrated into what we may consider the healthcare system organization.

The final customers of the healthcare service are patients and their families, and the final product is health. Health as a product is not easy to define and measure. A way to measure the product of healthcare systems is to look at their outcomes. Today, the outcomes of healthcare systems are considered to be economic, clinical, and humanistic in nature.

Pharmacists participate in the healthcare system and in its final product. Sometimes they directly access the patient, and other times, they indirectly access the patient through other health professionals (doctors, nurses), providing them with what belongs to us—our knowledge of drugs. Drugs are widely used as resources in all healthcare systems. Our objective would be to achieve a safer and effective medication-use process.

However, the healthcare system is only furnished with limited resources, facing endless new technologies and growing service demand by the population. All this translates into tremendous economic pressure on healthcare professionals.

This is the starting point in the development of the subject of quality assurance in pharmacy services.

ADVANCING TOWARD QUALITY

There are many definitions of quality;[1,3] however, we reduce the concept to the bare bones. That is, quality is doing things right, or better said, allowing our customers to receive good service because they, precisely, are the ones who rate the quality of the service (Fig. 1).

Here, we outline two basic questions:

1. *Who are the customers of the pharmacy service?* Patients, their relatives, physicians, nurses, society, managers and administrators, politicians, students, and so on are the customers. They do not always share the same values and can even have conflicting interests. This is due to agency relationships, so frequent in healthcare.

2. *Which are the services offered by the pharmacy service?* This question does not refer to what pharmacists do, how they invest their time, or what their tasks are—all that is well known. We know what is done, but it is more difficult to prove what it is for; that is, what is the usefulness for the patient? The question refers to what clients receive from pharmacy services, from their own point of view. As stated previously, what customers get is what makes sense to pharmaceutical organizations.

It is strategic for clinical pharmacy services to identify and segment customers to meet their expectancies and needs. It results in good customer management.

As a profession, the services we offer are not fully agreed upon or conceptualized, but delivery of medications, and manufacture and handling, are. These services are our baseline services. It is far more difficult to consensuate and conceptualize the pharmacists' cognitive services and their added value to health process, yet there have been some attempts.[4–6] The reason is likely to be that we are not paid to do that,[7] so we do not feel obligated to do so, unlike other professions with a great knowledge load.

We should find a way to accomplish it and offer a portfolio of services. This portfolio of pharmaceutical services should be patient oriented and customer focused. There are some works in the literature that describe the needs assessment with different customers (patients, healthcare teams, etc.).[7–11]

DOI: 10.1081/E-ECP 120006379

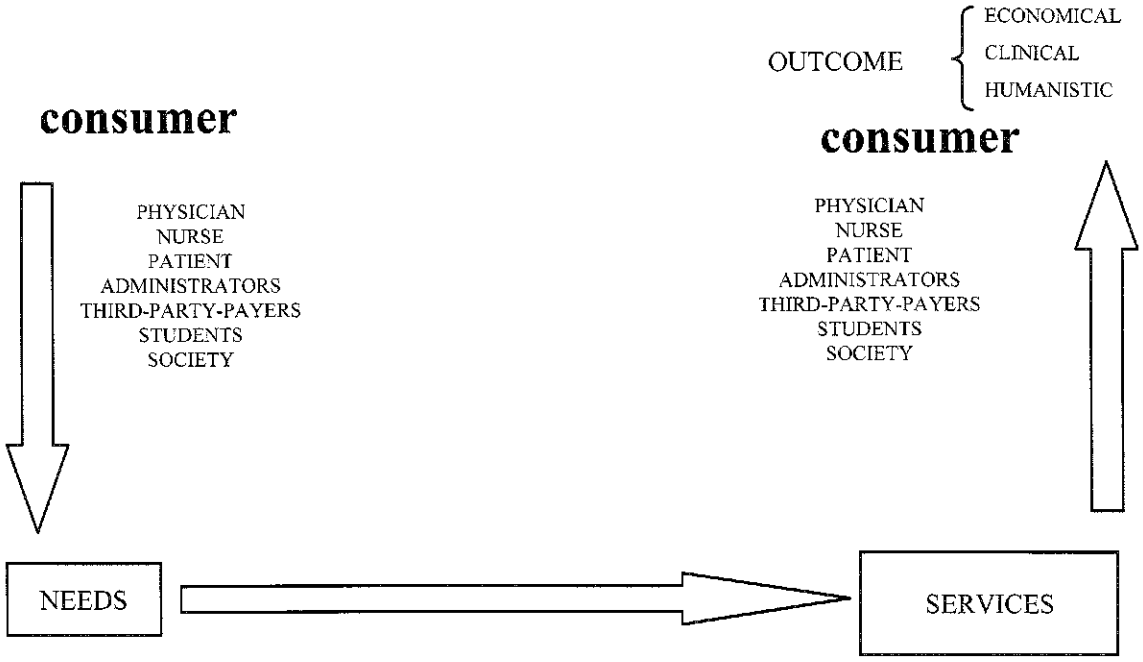

Fig. 1 Rating quality of service.

The next step is to define what the characteristics are of each service we offer in this portfolio. By these characteristics, we are defining the variables of quality itself. Quality would also include, besides technical aspects, those aspects related to communication skills, which are quite valued in customer satisfaction. The cognitive, behavioral, and emotional aspects of communication are thus considered.

In working toward quality, there are several steps and different tools:

- Certification.
- Accreditation.
- Self-evaluation.

Certification

The object of certification is to ensure that what is done is what was said would be done. In certification, we normalize both processes and procedures. A *process* is a sequence of activities performed to provide a service. The activity is what is done, whereas a *procedure* is the documentation that describes how to perform a process (a set of activities). A *service* is what the patient gets, and the *outcome* is the result of the service.

To provide our customers with these services, we are furnished with material and human resources that produce them. The production of services takes place by means of processes (Fig. 2). To obtain high-quality services, processes need to be very well defined, and to be known and accepted by those performing them. A good way to define them is using flowcharts.

Quality should never be improvised; quality is planned. Service production processes should be well defined. Those performing them should known them, and be well prepared and trained for this objective of quality. People want to work properly, so organizations should prepare the ground, clearly stating what it is expected from them, training them adequately, and commending that is done well.

In this normalization of processes, the activities to be performed should be defined, as well as their sequence and who does it and how.[12,13] This is a good time to incorporate technologies such as information system, robotics, communication systems, and so on.[14,15]

In the definition stage of this process, it is essential to be flexible, to have an open and imaginative mind, and to question everything—what is done, why, for what reason, and for whom (in these steps, some tasks are often found to be unnecessary and can be left undone because they provide nothing to the final service or are repeated; some activities are done just because it has always been that way). It is good to have a variety of people with different points of view, and it is advisable that the staff involved in the process also participate in it, whatever their train-

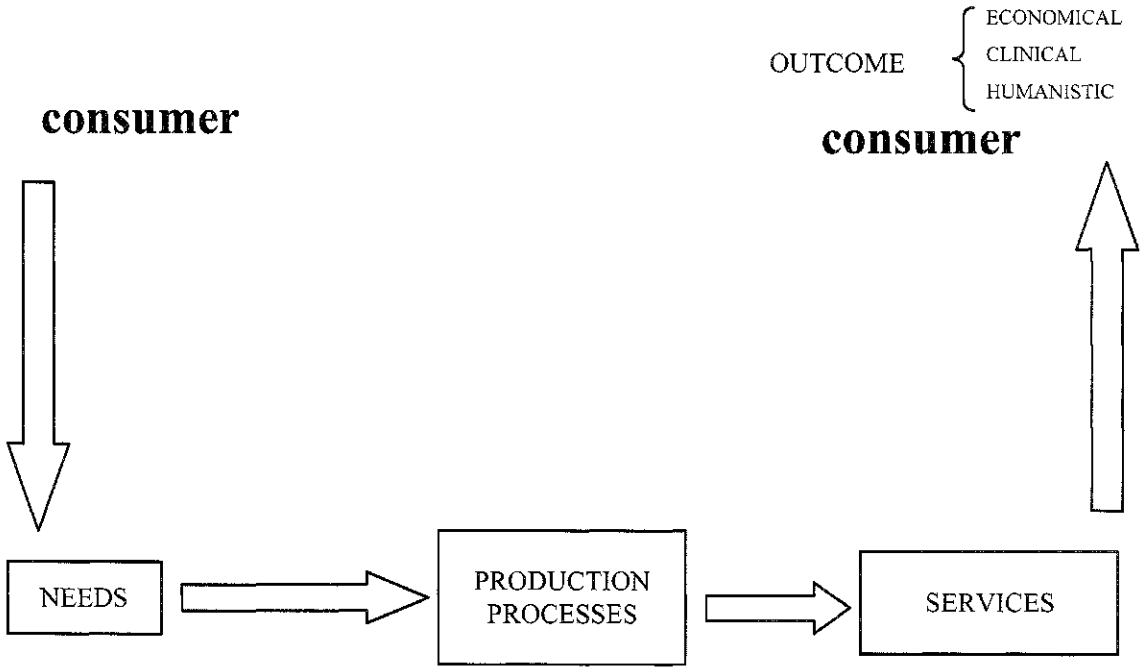

Fig. 2 Production of service by means of a process.

ing, because they are the ones who know their work best and know how to improve it. It has the advantage of facilitating empowerment, homogenizing criteria, and forcing the culture of quality to develop.

Once the process is defined, it simply has to be performed as described. The objective of this is to avoid variability in its execution and thus in its quality, depending on the person who performs it.

Everything should be normalized: process controls, equipment servicing, staff training, quality control (few indicators on critical points), frequency of the process review, and definition of responsibilities. The documentation of these activities should also be normalized.[16–18]

Processes normalization is distinct in each organization, because each organization is unique. This should be the second step toward quality. Defining our customers and our service portfolio is the first step. Each service should have a well-defined and normalized elaboration process, with a clear beginning and end.

So far we have discussed the operative processes—that is, the service production processes—but there are other equally relevant processes, such as support services (not perceived by the customer, but also essential, e.g., maintenance, purchases, etc.) and strategic services (they orient the whole organization; Fig. 3). The quality of all these processes is susceptible to evaluation.

Accreditation

Although certification ensures the homogeneity in the quality of organizations, accreditation is based on the creation of quality standards in service quality and in the comparison among several organizations.[19,20] Accreditation is granted by external organizations, which set the criteria and standards that are used as indicators of health. Before undergoing external accreditation, it is essential to know the requirements and to specifically prepare for them. An external accreditation is an acknowledgment that the quality requirements established by that organization are fulfilled. Actually, quality is predefined by means of indicators and standards. Accreditations may include structure, processes, and results standards. The current trend is toward the assessment of results, whenever possible.

Self-Evaluation

In self-evaluation, organizations enter a constant circle of questioning what they are doing, how, for whom, and how they can improve it. It involves an important degree of dynamism and maturity throughout the organization, with a clear, decided focus on the customer and society. It is a path toward excellence: the continuous culture of

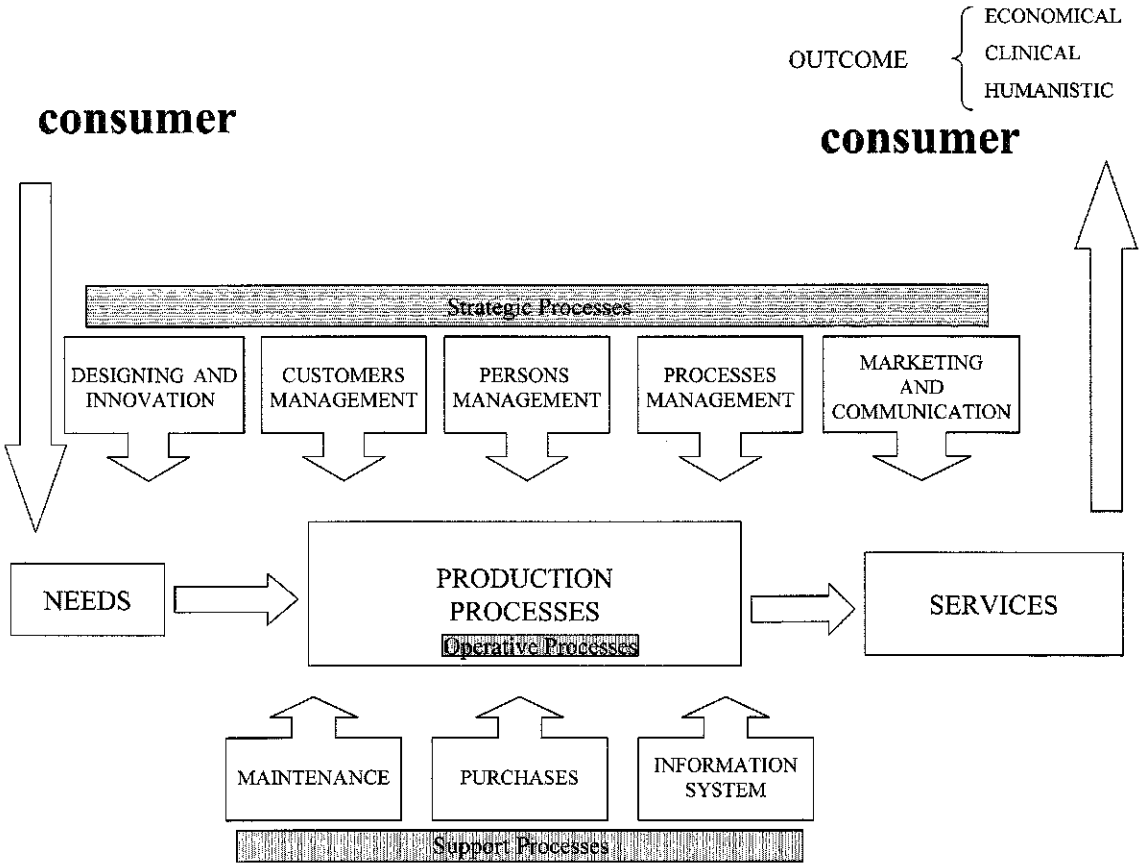

Fig. 3 Strategic, operative, and support processes.

quality. Their common feature is a proactive approach to quality. It deals with double-checking that what the organization designs is what customers really want and need, and if that it is precisely what the organization is actually providing.

At this level, we introduce concepts that are in vogue such as benchmarking and innovation. Both look for improvements in services and/or processes. The first concept does so by searching for better ways of working in other organizations; the second concept does so by means of imagination and creativity.

Benchmarking was first introduced in business science as an efficient and effective way of optimizing companies. It deals with looking for practices that proved successful in other companies, and implementing them into one's own company, or in plain words, copying the best ones.[21–24]

Innovation is the key to the future. It means to be alert as to how society, the healthcare system, and the macro- and micro-context in which we live, will evolve. An example of adaptation to the environment is the very concept of pharmaceutical care meant a great innovation for the profession,[25] and the contribution of the pharmacist in the detection and prevention of therapeutical errors, designing specific programs for it.[26,27]

In the healthcare sector, innovation is closely related to research and scientific evidence. We should increase our research on quality and also make it better.[28–32] Then, it has to be published and disseminated.[33] This should be done with high scientific level works, producing scientific evidence of quality. The study question should be less "how am I doing it?" (pharmacist oriented) and more "how do I improve the care offered to the patient?" (patient oriented).

KEY POINTS

Conceptualization and measurement are the key points. Quality management is achieved by the management of

customers, people, and processes. It is essential to follow a strategy because quality is not improvised. Conceptualization is what gives congruity to the whole system. In practice, this implies the following tactic.

Defining the Portfolio

Defining the portfolio of services and the level of quality of each service. Knowing the needs before designing and performing the service. Besides expressed needs (demand), we have to explore the hidden, or not expressed, needs. We should know what services and with what characteristics of quality are of interest to our customers, avoiding unnecessary efforts in services that will not be valued or that will be useless to us (although our unit may consider them interesting). In this section, qualitative research is a tool to consider. This is a strategic step.

Designing Process

It is important to design, or redesign the process so it fits the needs of each service.[34] Many of our pharmaceutical services are related to the production of clinical services. Considered with products, these services have many special characteristics to consider:

- They have a high content in customer care.
- Their main element is the human factor.
- Part of the quality of the service depends on the customer's perception.
- The satisfaction of the service provider is transmitted to the customer.
- Many services waste time while being produced, and the customer participates in its production (e.g., interviews with the customers). This means that the services cannot be stored or repeated. This is the concept of *servuction*, or production of services.
- Services can be personalized.
- Demand is not stable and is often unpredictable.

These conditions are especially met by services related to knowledge. This is why the human factor is so important in the quality of pharmaceutical services with high added value. It is essential to reach an agreement on criteria, continuous education, and documentation. The degree of outcomes we observe in our patients depends in great measure on this quality. Human quality potenciate the technical quality.

These services are of an intangible nature, so it is sometimes positive to introduce elements to make invisible operations visible (e.g., to develop a physical support allowing the customer to see it clearly). Ours is a multidisciplinary job, and this must be reflected not only in our research, but also in our attitude and daily work, as full patient-focused members of the healthcare team.[35,36]

We have to be readily accessible, both in terms of space and time. We have to leave pharmacy offices and go to the patient and the healthcare team.[37] We must clearly and firmly lead all those activities related to drugs because this is the knowledge field of our profession. Leadership has a lot to do with effectively communicating to influence others' actions, attitudes, beliefs, and so on. Pharmacy services must relocate themselves strategically as proactive agents in the healthcare team.

Dissemination

Disseminate by notifying the customer about our work, and any improvement of it (marketing). Pharmaceutical services should notify the value of the processes in which they are leaders, and it should be loud and clear.

Due to its very nature, the work of pharmacists is multidisciplinary, as they are full, patient-focused members of the healthcare team.[38,39] To the patient, integration of the different areas or specialists who provide care is desirable. It is also true for the healthcare system. It is fundamental, of course, not only to have extensive clinical and drug knowledge, but also communication, negotiation, and leadership skills, as well as specific training in clinical interviews, pertaining to the customer and to the specific situation within the exercise of the profession. The best way to make ourselves known is with our daily work. It is then that we should let the healthcare staff know it, participating in other professions' forums, in consumers' associations, teaching other professionals, and using different channels, including mass media.

A multidisciplinary team works in coordination, sharing both patients and responsibility, both in the patient's direct care and in planning such care. Quality is defined in care planning, such as clinical sessions, elaboration, implementation, follow-up and evaluation of protocols, clinical paths and clinical guidelines, participation in different clinical commissions, and so on. Clinical pharmacists must be recognized as leaders in all drug-related aspects. It is not a right, it must be earned.

In an automated, natural manner, but in different settings from the strictly pharmaceutical, clinical pharmacists integrate clinical research and publications, together with other professionals. This involves disseminating the services that clinical pharmacy has to offer.

Actually, all healthcare professionals should learn that the center of the healthcare system is the patient, and rather than classifying the patients' functions, what is important are those processes that provide an added value to the patients' health, and those who lead them. It means establishing alliances between members of the healthcare team. Perhaps we should start viewing the members of health teams as being coresponsible for care, and even incorporate patients themselves into the team, with a first-line role, taking active part in decisions. The clinical pharmacists' goal is for patients to see them as an ally, someone on whom they can rely.

Measure

It is important to have a discussion with the customer after delivering our service to ensure that, once started, this service effectively fulfills its mission (considering its three dimensions: economic, clinical, and humanistic, along with patient satisfaction). In practice, this means to measure. Pharmaceutical services have to be measurable to be self-evaluated, corrected, and improved.

We can measure quality in our activities and in the services we produce,[40,41] as well as the impact of our contribution to the outcomes of the healthcare system in terms of quality[42] (Fig. 4).

For economic outcomes, we can use pharmacoeconomy as the main tool.[43] There is a great variety of clinical indicators that we can relate to drugs efficacy and safety. These clinical indicators, obtained with designs from clinical epidemiology (observational and experimental),[44] are excellent to measure clinical outcomes. To obtain indicators for humanistic outcomes, such as satisfaction and quality of life, we have different tools, such as surveys, and different qualitative research methods (interviews, focus groups, etc.).[45–48]

Measuring wastes some resources, and the concept of cost-opportunity makes us cautious when tempted to measure whatever is at hand. We should measure little, and just what is critical (even monitoring and

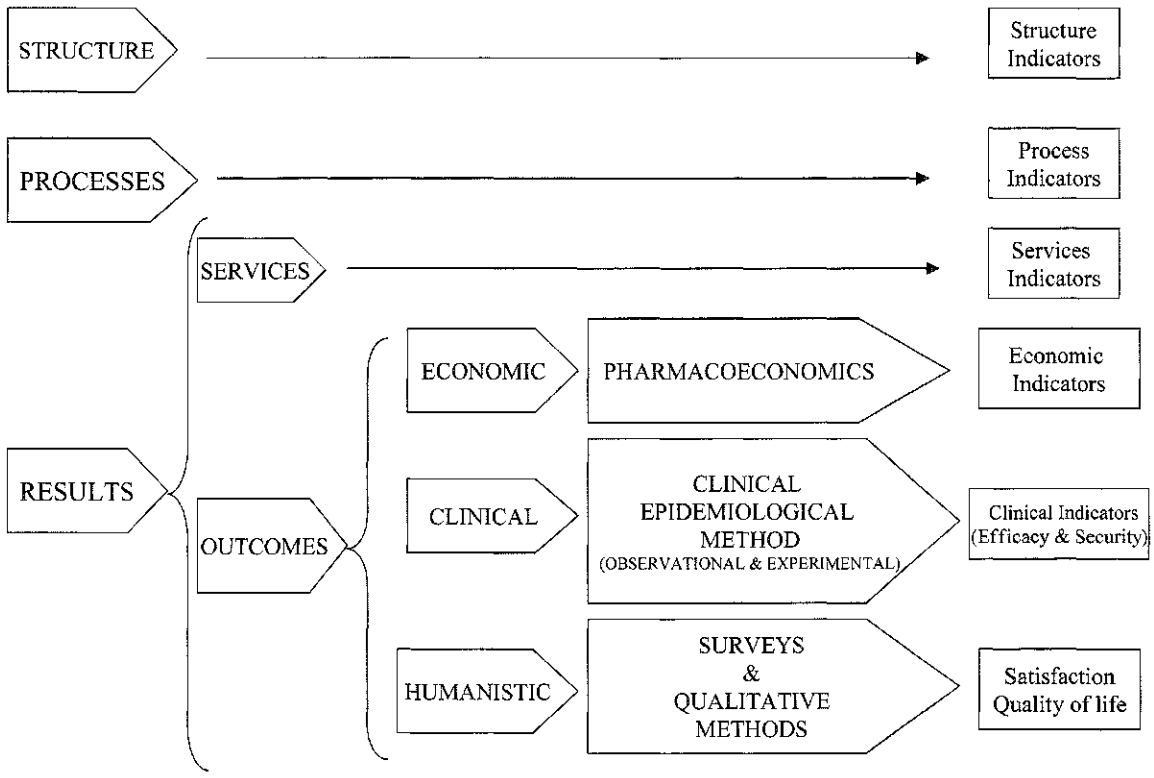

Fig. 4 Quality research.

measuring at a preestablished frequency) and/or important and significant. Before deciding to measure, we must be sure that we are using the best indicator as possible to reach our objective. We must know why and for what we are measuring—it is not the same to obtain a certification, make a decision, or research and publish.

The same criteria should be applied for technical questions of internal interest and for the clinical aspects of interest to the patient and the rest of healthcare staff. In this case, the language should be common to the rest of the healthcare staff, and indicators should be clinical indicators. This information, both positive or negative, has to be disseminated, clarified, and shared. We must insist on the use of clinical and satisfaction indicators, as well as of economic ones.

Feedback

Quality is something one pursues in an active manner. Once we start the path toward quality, we cannot abandon it: it just becomes part of our daily routine.

CONCLUSION

In this article, it was our intent to present a perspective on this topic, providing different tools to approach the quality of pharmaceutical services. These have been placed in a context where the concepts of limited resources, cost-opportunity, and efficacy are implicit. The concept has been abstracted so it can be applied to the public or private sectors, to hospital or ambulatory settings, and to different societies, with different values.

As for the external quality systems, we deliberately avoided the description of official quality systems, such as the Joint Commission on Accreditation of Healthcare Organizations (accreditation), International Standarization Organization (certification), and European Federation for Quality Management (self-evaluation), because it would have been impossible to cover them all. Instead, we abstracted the topic of quality, and all these external quality systems will probably assume most of the things discussed in this article.

Quality is planned and evaluated. In other words, quality is managed; it cannot be detached from management in its broader sense. Quality management is achieved by quality customers, people and process management. Quality varies according to the context and also with time. Quality is dynamic because the environment is dynamic. We must continuously adapt ourselves to the environment and innovate. What now is a gold standard will perhaps be a minimum tomorrow.

Quality is evaluated by measuring relevant indicators. Outcomes indicators (economic, clinical, and humanistic) will be the major importance in the future for clinical pharmacist services. Clinical pharmacist services must relocate themselves strategically as a proactive agent and lead drug therapy in the healthcare team.

The challenge will be the economic evaluation of pharmacy services. Once the products of pharmaceutical services and its outcomes are defined, considering economic, clinical, human outcomes, and once the minimal or standard quality if the services (both basic and value-added services, with high degree of knowledge), then we must know its cost.[49] In the context of healthcare systems, where they are currently immersed, with huge economic pressure, it is necessary to prove that the resources used by pharmaceutical services are cost effective for the healthcare system and the patient. In other contexts, and maybe in the future, it will be important to price these pharmaceutical services that our patients are going to receive.[50,51] By orienting our services through quality, they will probably be more effective, because we will not incur in the cost of nonquality.

We need to develop methods for measuring and meeting customers' expectations (needs and demands) to provide both baseline and value-added services, successful in kind and in quality. It is said we are in the age of knowledge. We pharmaceutics are well versed on the medications-use process. Let this knowledge be useful for our customers and society. Let us convey it in a clear, effective way. It is just quality.

REFERENCES

1. Deming, W.E. Calidad, productividad y competitividad. In *La salida de la crisis*; Diaz de Santos S.A.: Madrid, 1989.
2. Juran, J.M. El liderazgo para la calidad. In *Manual para directivos*; Diaz de Santos S.A.: Madrid, 1990.
3. Crosby, P. *La calidad no cuesta*; Compañía Editorial Continental S.A.: Mexico DF, 1990.
4. Ellis, S.L.; Billups, S.J.; Malone, D.C.; Carte, B.L.; Covey, D.; Mason, B.; Jue, S.; Carmichael, J.; Guthrie, K.B.S.; Sintek, C.D.; Dombrowski, R.; Geraets, D.R.; Amato, M. Types of interventions made by clinical pharmacist in the IMPROVE study. Pharmacotherapy **2000**, *20* (4), 429–435.

5. Maine, L.L. Pharmacy practice activity classification. J. Am. Pharm. Assoc. **1998**, *38* (2), 139–148.
6. Rudis, M.I.; Brandl, K.M. Position paper on critical care pharmacy services. Crit. Care Med. **2000**, *28* (11), 3746–3750.
7. Williams, S.E.; Bond, C.M.; Menzies, C. A pharmaceutical needs assessment in a primary care setting. Br. J. Gen. Pract. **2000**, *50*, 95–99.
8. Ruta, D.A.; Duffy, M.C.; Farquharson, A.; Young, A.M.; Gilmour, F.B.; McElduff, S.P. Determinig priorities in primary care: The value of practice-based needs assessment. Br. J. Gen. Pract. **1997**, *47*, 353–357.
9. Murie, J.; Hanlon, P.; McEwen, J.; Rusell, E.; Moir, D.; Gregan, J. Needs assessment in primary care: General Practitioners' percepcions and implications for the future. Br. J. Gen. Pract. **2000**, *50*, 17–20.
10. Hanlon, P.; Murie, J.; McEwen, J.; Moir, D.; Russell, E. A study to determine how needs assessment is being used to improve health. Public Health **1998**, *112*, 343–346.
11. Jordan, K.; Ong, B.N.; Croft, P. Researching limiting long-term illness. Soc. Sci. Med. **2000**, *50*, 397–405.
12. Kassam, R.; Farris, K.B.; Cox, C.E.; Volume, C.I.; Cave, A.; Schopflocher, D.P.; Tessier, G. Tools used to help community pharmacist implement comprehensive pharmaceutical care. J. Am. Pharm. Assoc. **1999**, *39* (6), 843–856.
13. Holdford, D.A.; Kennedy, D.T. The service blueprint as a tool for designing innovative pharmaceutical services. J. Am. Pharm. Assoc. **1999**, *39* (4), 545–552.
14. Gulliford, S.M.; Schneider, J.K.; Jorgenson, J.A. Using telemedicine technology for pharmaceutical services to ambulatory care patients. Am. J. Health-Syst. Pharm. **1998**, *55*, 1512–1515.
15. Bates, D.W. Using information technology to reduce rates of medication errors in hospitals. BMJ **2000**, *320*, 788–791.
16. Strand, L.M.; Cipolle, R.J.; Morley, P.C. Documenting the clinical pharmacists' activities: Back to basics. Drug Intell. Clin. Pharm. **1998**, *22*, 63–67.
17. Canaday, B.R.; Yarborough, P.C. Documenting pharmaceutical care: Creating a standard. Ann. Pharmacother. **1994**, *28*, 1292–1296.
18. Overhage, J.M.; Lukes, A. Practical, reliable, comprehensive method for characterizing pharmacists' clinical activities. Am. J. Health-Syst. Pharm. **1999**, *56*, 2444–2450.
19. Godwin, H.N. Achieving best practices in health-system pharmacy: Eliminating the "practice gap". Am. J. Health-Syst. Pharm. **2000**, *57*, 2212–2213.
20. Rupp, M.T. Establishing realistic performance standards for community pharmacists' drug-use—review activities in managed care contracts. Am. J. Health-Syst. Pharm. **1999**, *56*, 566–567.
21. Tweet, A.G.; Gavin-Marciano, K. *The Guide to Benchmarking in Healthcare*; Quality Resources, Kraus Org: New York, 1998.
22. Knoer, S.J.; Couldry, R.J.; Folker, T. Evaluating a benchmarking database and identifying cost reduction oportunities by diagnosis-related group. Am. J. Health-Syst. Pharm. **1999**, *56*, 1102, 1107.
23. Bhavnani, S.M. Benchmarking in health-system pharmacy: Current research and practical applications. Am. J. Health-Syst. Pharm. **2000**, *57* (Suppl. 2), S13–S20.
24. Murphy, J.E. Using benchmarking data to evaluate and support pharmacy programs in health-systems. Am. J. Health-Syst. Pharm. **2000**, *57* (Suppl. 2), S28–S31.
25. Heppler, C.D.; Strand, L.M. Opportunities and responsibilities in pharmaceutical care. Am. J. Hosp. Pharm. **1990**, *47*, 533–543.
26. Khon, L.T.; Corrigan, J.M.; Donaldson, M.S. *To Err is Human. Building a Safer Health System*; National Academy Press: Washington, DC, 1999.
27. Manasse, H.R. Pharmacist and the quality-of-care imperative. Am. J. Health-Syst. Pharm. **2000**, *57*, 1170–1172.
28. Vermeulen, L.C.; Beis, S.J.; Cano, S.B. Applying outcomes research in improving the medication-use process. Am. J. Health-Syst. Pharm. **2000**, *57*, 2277–2282.
29. Indritz, M.E.S.; Artz, M.B. Value added to health by pharmacist. Soc. Sci. Med. **1999**, *48*, 647–660.
30. Rogers, S.; Humphrey, C.; Nazareth, I.; Lister, S.; Tomlin, Z.; Haines, A. Designing trials of interventions to change professional practice in primary care: Lesson from an exploratory study of two change strategies. BMJ **2000**, *320*, 1580–1583.
31. White, K.L. Fundamental research at primary care level. Lancet **2000**, *355*, 1904–1906.
32. Park, G.D.; Ball, W.D. Problems with evaluations of clinical pharmaceutical services. Am. J. Hosp. Pharm. **1980**, *37*, 1290–1291.
33. Singhal, P.K.; Raisch, D.W.; Gupchup, G.V. The impact of pharmaceutical services in community and ambulatory care settings: Evidence and recommendations for future research. Ann. Pharmacother. **1999**, *33*, 1336–1355.
34. Schumock, G.T.; Michaud, J.; Guenette, A.J. Re-engineering: An opportunity to advance clinical practice in a community hospital. Am. J. Health-Syst. Pharm. **1999**, *56*, 1945–1949.
35. Franic, D.; Pathak, D.S. Situational factors as predictors of pharmaceutical care in a community setting: An application of the adaptive decision-making model. Pharm. Pract. Manage. Q **1999**, *18* (4), 19–28.
36. Nimmo, C.R.; Jewesson, P.J. Documenting pharmacists' activities in the health record: A mechanism to provide ongoing quality assurance. Ann. Pharmacother. **1993**, *27*, 1405–1406.
37. Campbell, R.K.; Saulie, B.A. Providing pharmaceutical care in a physician office. J. Am. Pharm. Assoc. **1998**, *38*, 495–499.

38. Monk-Tutor, M.R. Pharmacist too reluctant to promote services. J. Am. Pharm. Assoc. **1998**, *38*, 389–391.
39. Spalek, V.H.; Gong, W.C. Pharmaceutical care in an integrated health system. J. Am. Pharm. Assoc. **1999**, *39*, 553–557.
40. Zimmerman, C.R.; Smolarek, R.T.; Stevenson, J.G. Peer review and continous quality amprovement of pharmacists' clinical interventions. Am. J. Health-Syst. Pharm. **1997**, *54*, 1722–1727.
41. ASPH report. Summary of the final report of the ASPH quality assurance indicators development group. Am. J. Hosp. Pharm. **1992**, *49*, 2246–2251.
42. Lipowski, E.E. Evaluating the outcomes of pharmaceutical care. J. Am. Pharm. Assoc. **1996**, *NS36* (12), 726–734.
43. Sanchez, L.A. Applied pharmacoeconomics: Evaluation and use of pharmacoeconomic data from literature. Am. J. Health-Syst. Pharm. **1999**, *56*, 1630–1638.
44. Fisher, L.R.; Scott, L.M.; Boonstra, D.M.; DeFor, T.A.; Cooper, S.; Eelkema, M.A.; Hase, K.A.; Wei, F. Pharmaceutical care for patients with chronic conditions. J. Am. Pharm. Assoc. **2000**, *40*, 174 -180.
45. Schommer, J.C.; Kucukarslan, S.N. Measuring patients satisfaction with pharmaceutical services. Am. J. Health-Syst. Pharm. **1997**, *54*, 2721–2732.
46. Green, J.; Briteen, N. Qualitative research and evidence based medicine. BMJ **1998**, *316*, 1230–1232.
47. Mays, N.; Pope, C. Observational methods in healthcare settings. BMJ **1995**, *311*, 182 -184.
48. Carroll, N.V.; Gagnon, J.P. Parmacists' perceptions of consumers demand for patient-oriented pharmacy services. Drug Intell. Clin. Pharm. **1984**, *18*, 640–644.
49. George, B.; Silcock, J. Economic evaluation of pharmacy services—fact or fiction? Pharm. World Sci. **1999**, *21* (4), 147, 151.
50. Hawksworth, G.M.; Chrystyn, H. Clinical pharmacy in primary care. Br. J. Clin. Pharmacol. **1998**, *46*, 415–420.
51. Susla, G.; Masur, H. Critical care pharmacist: An essential or a luxury. Crit. Care Med. **2000**, *28*, 3770–3771.

Residencies

R

Donald E. Letendre
American Society of Health-System Pharmacists, Bethesda, Maryland, U.S.A.

INTRODUCTION

A pharmacy residency is an organized, directed, postgraduate training program in a defined area of pharmacy practice. Residencies exist primarily to train pharmacists (called "residents" during the training program) by providing them the opportunity to accelerate their growth beyond entry-level professional competence in direct patient care and in practice management, and to further the development of leadership skills that can be applied in any position and in any practice setting. Pharmacy residents acquire substantial knowledge required for skillful problem solving, refine their problem-solving strategies, strengthen their professional values and attitudes, and advance the growth of their clinical judgment, a process begun in the clerkships of the professional school years but requiring further extensive practice, self-reflection, and shaping of decision-making skills based on feedback on performance. The residency provides a fertile environment for accelerating growth beyond entry-level professional competence through supervised practice under the guidance of model practitioners. Residents are held responsible and accountable for pursuing optimal medication therapy outcomes in patients.

The residency also provides a fertile environment for accelerating the growth of residents' leadership skills. Each residency offers the opportunity to exercise leadership under the watchful eye of effective leaders. Examples of leadership skills and traits that may be enhanced during a residency include trustworthiness and integrity, comfort with ambiguity, organizational commitment, cross-cultural sensitivity, internalization of the role of service to patients and other customers, recognizing the need for change, change management, persuasive communication, team-building, confidence in one's ability to lead, and realistic self-assessment. To ensure continuous development of future leaders in pharmacy practice, it is widely accepted that leadership skill development be an integral part of pharmacy practice residency training.

TYPES OF RESIDENCIES

There are two types of residency programs: pharmacy practice and specialized. Pharmacy practice residencies, often referred to as "general" residencies, are intended to provide training and education in the fundamentals of exemplary contemporary pharmacy practice. Areas in which the resident typically receives training are acute patient care, ambulatory patient care, drug information and drug-use policy development, and practice management. Because pharmacy practice residencies are offered in a variety of practice settings (e.g., hospitals, health systems, home care programs, long-term care facilities, managed care environments, community practice sites), the relative time that the resident might spend in each area of practice will likely vary depending on the nature of the site and the types of patients being served, as well as the particular practice interests of the resident. Fundamentally, pharmacy practice residencies are intended to produce a well-grounded general clinical pharmacy practitioner.

Specialized residencies are offered in a wide variety of specialty practice areas and are intended to build upon the practice experience gained through completion of a pharmacy practice residency. The following is a list of specialized areas of practice in which American Society of Hospital Pharmacists (ASHP)-accredited residency programs are offered:

- Critical care
- Drug information
- Emergency medicine
- Geriatric
- Infectious diseases
- Internal medicine
- Managed care
- Nuclear
- Nutritional
- Oncology
- Pediatric
- Pharmacotherapy

Encyclopedia of Clinical Pharmacy
DOI: 10.1081/E-ECP 120006359

- Pharmacy practice management
- Primary care
- Psychiatric
- Subspecialities (e.g., cardiology, pulmonary, renal)

ACCREDITATION—WHAT DOES IT MEAN?

ASHP, in cooperation with its professional association partners, administers the only process that grants accreditation status to practice sites conducting residencies. ASHP's authority to grant accreditation is recognized by the Health Care Financing Administration (HCFA). The accreditation process requires that each site demonstrate compliance with established standards of practice and offer a residency that meets the requirements for training.

The process of accreditation ensures that accredited programs are peer reviewed and that requirements for providing a state-of-the-art practice environment are fulfilled.

EVOLUTION OF RESIDENCIES

The Early Years

One of the fundamental issues that led to the founding of the ASHP in 1942 was the need to train practitioners for hospital pharmacy. This segment of practice was largely ignored by pharmaceutical education. The first proposed standard for postgraduate pharmacy training was published for comment in ASHP's *The Bulletin* in 1948.[1] Since then, the requirements for training, as reflected in the accreditation standards that have evolved throughout the years, have always attempted to challenge programs to be at the vanguard of practice.

The initial pharmacy residencies—or "internships" as they were called—were established in the 1930s, first at the University of Michigan Hospital in Ann Arbor under the direction of Harvey A. K. Whitney and Edward C. Watts. Other early programs were at the University of California Hospital in San Francisco, Duke University Hospital, and St. Luke's in Cleveland. By the early 1950s, it was estimated that at least a dozen hospitals offered hospital pharmacy internship training.[2] In December 1962, preceptors of the programs in existence at the time and other hospital pharmacy leaders convened a meeting that in retrospect helped set the framework for the accreditation process that is in use today. At that meeting, the term "residency" was first adopted (replacing the term "internship") and participants agreed on a set of standards that would be used to conduct the first accreditation site surveys in the spring of 1963.

Throughout the early years, postgraduate pharmacy training, as reflected in the standards, focused primarily on the manufacture and preparation of pharmaceutical products and on systems that could be implemented to help ensure the integrity of those products up to the point of administration. Moreover, substantial effort was placed on providing trainees with the skills needed to pursue leadership roles in the hospital pharmacy community. The standards used to guide postgraduate training in institutional settings during the early years were reflective of practice at that time in that they focused heavily on the "product" side of the profession with little mention of the end user, the patient.

Clinical Pharmacy Emerges

In the late 1960s and early 1970s, a few residency programs began to place greater emphasis on patient care. Clearly, these programs provided a philosophical shift away from product-focused training and toward a greater emphasis on pharmacist participation in patients' drug therapy management. They also helped facilitate the "clinical pharmacy" movement that was emerging by providing training to many of the early would-be clinical pharmacy pioneers. The rapidity with which change was occurring is perhaps best reflected in the *Clinical Services* segment of the Qualifications of the Pharmacy Service section of the revised Accreditation Standard for Pharmacy Residency in a Hospital that was approved in November 1974:[3]

The functions which comprise clinical services are difficult to identify, partly because there is no common agreement among practitioners as to the definition of a clinical *service*, partly because there are "clinical" components associated with most, if not all, of the service functions of the hospital pharmacy department, and partly because, in current practice, no clear distinction has been made between clinical *teaching* activities and clinical *service* activities. What are frequently purported to be service activities are, more often than not, teaching (or learning) activities. For this reason, in evaluating clinical *service* activities, only those services...which are continuously performed even in the absence of students and trainees, are considered.

This document marked the first time that requirements for clinical pharmacy services in postgraduate training programs were addressed. Nonetheless, over the

next few years, it became increasingly more difficult to evaluate the growing number of "clinical residencies" that were emerging against the hospital pharmacy accreditation standard. In those programs, the scope of clinical services provided to patients grew substantially and the attendant requirements for residency training to assist in the delivery of those services were not addressed adequately in the accreditation standard—it was like trying to fit the proverbial square peg in a round hole. Hence, in 1980, ASHP approved the first Accreditation Standard for Residency Training in Clinical Pharmacy.[4]

Maintaining accreditation standards for both hospital and clinical residencies throughout the 1980s was beneficial for a variety of reasons. Among them were the following:

1. *The profession's differentiated workforce needs.* Many staff pharmacist positions in organized health care settings required a blend of the administrative and clinical skills that graduates of general hospital residencies received, whereas most management positions required graduates to complete hospital residencies that focused primarily on honing a resident's administrative skills (most often these were tied to MS degree programs). However, graduates of clinical residencies typically pursued faculty appointments and clinical practice positions that provided greater opportunities to deal directly with patients' drug therapy issues.
2. *An insufficient level of residency candidates holding advanced degrees.* A prerequisite to pursuing a clinical residency was the completion of the PharmD degree or a commensurate level of life experience to satisfy this requirement. Although the number of pharmacy school graduates holding the PharmD degree continued to increase throughout the 1980s, several clinical residencies struggled early on to obtain only candidates who had satisfied this prerequisite. This situation was particularly noteworthy for programs that were in regions where there was a paucity of PharmD graduates.
3. *Qualifications of the pharmacy service.* Virtually all departments of pharmacy that offered general hospital residency training in the 1980s provided some level of clinical pharmacy services. However, for the majority of these programs, the level of clinical services provided—particularly during the early 1980s—was inadequate to meet the requirements of the clinical residency accreditation standard. Hence, providing programs with sufficient time to establish these services under the direction of clinically competent practitioners was a key factor in maintaining both the hospital and the clinical tracks in residency training.

Specialization

The training of clinical specialists and pharmaceutical scientists took hold in the 1970s and progressed throughout the 1980s, paralleling advances in drugs and drug delivery systems. Outgrowths of this movement included the birth of the Board of Pharmaceutical Specialties and the American College of Clinical Pharmacy (ACCP), and the establishment of the ASHP Special Interest Groups (SIGs). Throughout this period, it became increasingly more accepted in the profession that pursuing optimal drug therapy in patients, particularly when extremely complex drug regimens were involved, often required a more sophisticated level of service than was typically provided by a general pharmacy practitioner. Spurred on by the increasing need for more highly trained individuals, in 1980, ASHP approved the first Accreditation Standard for Specialized Pharmacy Residency Training[5] (frequently referred to as the specialized "umbrella" standard) and the Supplementary Standard and Learning Objectives for Residency Training in Psychiatric Pharmacy Practice,[6] which had been developed by the SIG on psychopharmacy practice. Since then, supplemental standards have been approved for 16 specialized areas of pharmacy practice. Two of these standards, pharmacotherapy and infectious diseases, were developed jointly with the ACCP and the Society of Infectious Disease Pharmacists, respectively.

Pharmacy Practice Residencies

ASHP approved the Long-Range Position Statement on Pharmacy Manpower Needs and Residency Training[7] at the same time as the clinical residency standard. The position statement intended to guide the thinking of members about the categories of professional and technical pharmacy workforce needed in organized health care settings and the types of training programs required to meet that need. It also acknowledged that over time the distinction between a "generalist" and a "clinical practitioner" would diminish and that, at some point in the future, the need to maintain both clinical and hospital residency standards would no longer exist.

Consistent with this thinking, practitioners at the 1985 Hilton Head Conference on "Directions for Clinical Practice in Pharmacy"[8] and the 1989 National Residency Preceptors Conference[9] offered several recommendations to merge the hospital and clinical residency standards. In particular, participants at these conferences noted that, due to revisions in the hospital and clinical residency standards, major segments of both documents, especially those that relate to requirements in departmental services, were now virtually identical. Moreover, it was also noted that portions of the requirements in the general hospital standard—notably, the training objectives for the clinical and drug information services areas—approached the clinical standard more closely than in the past. Hence, in 1991, following more than 2 years of development that included a series of open forums to receive input from residency preceptors on all proposed segments of the document, the first Accreditation Standard for Residency in Pharmacy Practice was approved.[10]

Adoption of the term "pharmacy practice" in the new standard was significant. Clear consensus was established that the time had come to no longer distinguish between "clinical pharmacy practice" and "pharmacy practice" as the practice of pharmacy is inherently clinical.[11] As of July 1, 1992, all ASHP-accredited general hospital and clinical residencies were converted to residencies in pharmacy practice. Since then, three separate standards governing pharmacy practice residencies have emerged: ASHP Accreditation Standard for Residencies in Pharmacy Practice (approved April 25, 2001); Accreditation Standard and Learning Objectives for Residency Training in Pharmacy Practice (with Emphasis in Community Care), prepared jointly by ASHP and the American Pharmaceutical Association; and Accreditation Standard and Learning Objectives for Residency Training in Managed Care Pharmacy Practice, prepared jointly by ASHP and the Academy of Managed Care Pharmacy.

PREREQUISITES FOR TRAINING

In all instances, the applicant to a residency must be a highly motivated pharmacist who desires to obtain advanced education and training, leading to an enhanced level of professional practice. The applicant must be a graduate of a college of pharmacy accredited by the American Council on Pharmaceutical Education or be otherwise eligible for licensure.

A residency in pharmacy practice is predicated on prior clerkship and externship experiences. For this reason, applicants to this type of program should have completed a comprehensive clerkship and externship program such as is required in contemporary clinically based pharmacy curricula. For pharmacy practice residencies, there is no absolute requirement concerning the type of pharmacy degree the applicant must possess. However, it is clear that the PharmD degree provides the applicant with the level of knowledge and skills needed to meet the requirements for training in a pharmacy practice residency and that, over time, this degree is expected to become an absolute prerequisite for applicants. In all cases, it is the residency program director's responsibility to assess each applicant's baseline knowledge and skills, and to ascertain overall qualifications for admission. The applicant should bear in mind that it is permissible for programs to establish more stringent entry-level requirements; hence, applicants must take responsibility for contacting programs directly to determine specific entry requirements.

Prerequisites for entry into a specialized residency may vary depending on the type of program. In all instances, however, completion of the PharmD degree (or other advanced degree in pharmacy) is required, except in unusual cases (e.g., BS degree graduate who has been in practice several years). Although completion of a pharmacy practice residency is required typically for admission to a specialized program, some programs may accept an applicant without residency training provided that the individual has a comparable level of professional practical experience. The reason for this requirement is that a specialized program requires the applicant to have a sound foundation in general practice skills that the pharmacy practice residency provides. Applicants interested in pursuing specialized residency training are urged to contact programs directly to determine the specific requirements for application.

INFORMATION ON RESIDENCIES

There are a number of ways to learn about residencies. However, the avenues that will likely provide potential applicants with the most information are the *ASHP Residency Directory*, the *ACCP Directory of Residencies and Fellowships*, and the ASHP Residency Showcase. The *ASHP Residency Directory* is a two-volume series: Volume I covers pharmacy practice residencies and volume II covers specialized residency programs. This series is available through most colleges of pharmacy's departments of pharmacy practice and can be obtained directly following application to the ASHP Resident Match Program. The *ACCP Directory of Residencies and*

Fellowships is likewise available through most colleges of pharmacy and can be obtained directly by contacting ACCP. Both directories provide interested individuals with a wealth of pertinent program information. Individuals interested in learning more about the residency resources offered by these associations are encouraged to visit the following web sites: www.ashp.org and www.accp.com. Moreover, the following web sites offer specific information about community-based and managed care residencies, respectively: www.aphanet.org and www.amcp.org.

All students who are in their last year of pharmacy school and are interested in residency training are encouraged to attend the ASHP midyear clinical meeting in December of each year to participate in the Residency showcase. The showcase is an area set up in booth format that enables representatives of the various programs to meet personally with prospective residency candidates to address any questions they might have about a program. Among other things, it provides applicants with the best opportunity to meet preceptors and residents from each program, learn first hand about specific elements of each program, and gain insights into programs that are often difficult to obtain through the directories. Because virtually all programs require candidates to participate in on site interviews, participation in the showcase can help a prospective candidate better identify those programs of greatest interest, which will help minimize unnecessary travel expenses that might have otherwise been incurred traveling to a less desirable program. It is important to note that more than 98% of all ASHP-accredited residencies typically participate in the showcase.

Before searching for a residency, the pharmacist graduate must determine his or her career objectives. Because programs vary in terms of their relative degree of emphasis in the areas in which training is provided, it is particularly important for the applicant to determine, to the extent possible, the area(s) that are most suited to achieving career objectives. For example, an individual interested in some dimension of ambulatory care would be wise to pursue programs that offer a broad range of experiences in this area of practice.

It is not uncommon for career objectives to change following experience in the many areas of practice typically provided in residencies. Hence, for applicants who are unsure about future professional goals, the best advise is to pursue training in a practice site that provides a solid grounding in patient care because many of the skills a resident will acquire are transferable across most areas of pharmacy practice. To this end, it is essential that potential applicants allow adequate time to review program information, as well as ask program representatives about the overall strengths and weaknesses of their program. Frequently, the best assessment of what a program has to offer is through communication with residents currently in the program.

RESIDENT MATCHING PROGRAM

Virtually all pharmacy practice residencies are required to participate in the Resident Matching Program (RMP). The only exception is those programs offered through the military and public health services. Hence, it is essential that potential applicants to these programs register for the match. Applicants to specialized programs are not required to participate in the RMP.

ASHP contracts with the National Matching Service (NMS) to operate the RMP. The RMP ensures that each pharmacy practice residency program is matched with the preferred individuals who have applied and who have selected the program as an acceptable site in which to train. To apply for the match, applicants must contact NMS directly (595 Bay Street, Suite 300, Toronto, Ontario, Canada; telephone: 416-977-3431 or fax: 416-977-5020). There is a modest application fee, and the applicant agreement form must be received by January 15. Once NMS has received the agreement form, the applicant will be sent a personalized match number (this number will be required by all pharmacy practice residencies to which the student graduate applies) and, under separate cover, a copy of the *ASHP Residency Directory*. As noted previously, the Directory provides descriptions of all accredited programs, including important contact information. After consulting the Directory and identifying programs of interest, the student graduate must request applications forms directly from the individual residency program directors, not from ASHP. Most programs require the applicant to participate in an on-site interview; hence, student graduates are advised to check directly with programs about application procedures as policies governing application do vary among programs.

REFERENCES

1. Fiske, R., et al. Standards for internships in hospital pharmacies. The Bulletin **September/October 1948**, *5* (5), 233–234.
2. Zellmer, W.A. Twenty-Five Years of Pharmacy Residency Accreditation—Part I. Early Efforts to Establish the Program (Unpublished manuscript).

3. Accreditation standard for pharmacy residency in a hospital. Am. J. Hosp. Pharm. **February 1975**, *32*, 192–198.
4. ASHP accreditation standard for residency training in clinical pharmacy. Am. J. Hosp. Pharm. **September 1980**, *37*, 1223–1228.
5. ASHP accreditation standard for specialized pharmacy residency training. Am. J. Hosp. Pharm. **September 1980**, *37*, 1229–1232.
6. ASHP supplementary standard and learning objectives for residency training in psychiatric pharmacy practice. Am. J. Hosp. Pharm. **September 1980**, *37*, 1232–1234.
7. ASHP long-range position statement on pharmacy manpower needs and residency training. Am. J. Hosp. Pharm. **September 1980**, *37*, 1220.
8. Directions for clinical practice in pharmacy. Proceedings of an invitational conference conducted by the ASHP Research and Education Foundation and the American Society of Hospital Pharmacists. Am. J. Hosp. Pharm. **June 1985**, *42*, 1287–1342.
9. Directions for postgraduate pharmacy residency training. Proceedings of the 1989 National Residency Preceptors Conference conducted by the American Society of Hospital Pharmacists. Am. J. Hosp. Pharm. **January 1990**, *47*, 85–126.
10. ASHP accreditation standard for residency in pharmacy practice. Am. J. Hosp. Pharm. **January 1992**, *49*, 146–153.
11. Letendre, D.E. Reflections on the future of pharmacy residency programs: An ASHP perspective. Am. J. Pharm. Educ. **Fall 1992**, *56*, 298–300.

Role of the Clinical Pharmacist in Clinical Trials (Spain)

Josi-Bruno Montoro-Ronsano
Hospital General Vall d'Hebron, Barcelona, Spain

INTRODUCTION

The development of a new drug, from its initial synthesis until its approval and registration by the regulatory agency, goes through different stages in which clinical trials are of paramount importance. The use of any drug in humans requires the fulfillment of previous valid clinical trials, which ensure the efficacy and safety of the drug and guarantee that the basic ethical rights concerning the patients are respected.[1]

The pharmaceutical industry supports much of the drug research in Spain, as it occurs in other countries.[2] The main goal of most clinical trials initiated is to achieve data on the efficacy and safety of a research drug, to complete the corresponding file, and to present it to the regulatory agency for its approval. Clinical research represents a major component of investment and development activity and takes an appreciable 36% of the research and development budget. This amount is similar to those corresponding to the European Community (39%) and to the world as a whole (36%).[3] It is important to notice that since the 1980s the activity in clinical research, and consequently the number of clinical trials that have been developed, has increased continuously. Concretely, the number of clinical trials developed in Spain has increased from 88 during the period 1987–1989 to 520 in 2000 (until November).[1,4,5]

From the profile of clinical trials developed in Spain, different descriptive studies allow us to obtain a precise picture. Most of the protocols evaluated are phase III (i.e., designed to fulfill the registration schedule and get the approval of the regulatory agency) (42% and 49%, depending on the descriptive study), multicenter (79% and 98%), controlled (76% and 82%), and double-blind (42% and 52%).[6,7] According to the therapeutic activity of the investigational drug, the most frequent groups were anti-infective and antineoplastic drugs.

Currently, as pointed out by Lunik,[8] clinical trials are a matter of great importance in the world of health care. There are many sophisticated compounds under development, with specific properties and unique storage, preparation and monitoring requirements. The need for clinical sites that can undertake quality research and the need for health professionals who are able to manage the more complex protocols is outstanding. Moreover, clinical trials have been put on aggressive time-to-development schedules. In addition, the research process has become globalized, and efforts have been made to standardize good clinical practices (GCP) among the developed communities.

Within this context, clinical pharmacists face effective participation in the research environment. Protocol development and execution, adherence to GCP and ethical principles, together with the balance between revenues and expenses, draw a specific working scenario that requires additional education and training, and represents an emerging challenge for clinical pharmacists. Conceptually, pharmacists are responsible for the safe and effective use of all medications, and this is especially important for medications used in clinical trials.[9] Different pharmacy associations have been pointed out and have defined how far drug development and its attendant activities are a core function of the pharmacy profession.[10–12]

Although regulations and recommendations currently in force in Spain assign the responsibility for studied drugs to the investigator and the promoter–sponsor, rather than the pharmacy service, it is clearly established that the management of the samples for investigation must be performed by the pharmacy. From this point of view, the development of pharmacy-based investigational drug services (the so-called Unidades de Ensayos Clínicos) has been extensive, and more interestingly, the concept that clinical trials represent a clear opportunity to expand the role of the clinical pharmacist, has been widely understood. Nevertheless, the attitude and participation of pharmacists in clinical trials is not homogeneous within the different hospitals. Passive reactions to innovate in this field can still be detected, and the pharmacists' training in many cases is not optimal, especially with a lack of standardized guidelines for training residents.

REGULATORY ISSUES

The development and achievement of clinical trials is based on ethical postulates, specific legislation in use, and international guidelines for GCP research.

The assessment of health technologies is placed under the Ley General de Sanidad.[13] This evaluation is guided to determine the health, social, and economic impacts of the new technology under scrutiny, and is compared with other alternative interventions. According to the Ley del Medicamento,[14] a clinical trial is defined as experimental evaluation of a substance or a drug, by means of its administration or application to human, oriented to any of the following targets:

- To point out its pharmacodynamic or pharmacokinetic effect.
- To establish its efficacy for a given therapeutic, prophylactic, or diagnostic indication.
- To define its adverse effects profile and establish its safety.

The term "experimental evaluation" refers to studies that test substances nonauthorized as proprietary medicine products or proprietary medicine products used in nonauthorized conditions.

Clinical trials may only be carried out when all the following principles have been complied with:

- The preclinic data about the product under study are reasonably sufficient to guarantee that risks to the subjects on whom the trial is conducted are admissible.
- The study is based on current available data, and the research represents, or may represent, an improvement of scientific knowledge about humans or an improvement of human health, and by its design should minimize the risk to the subjects.
- The interest of the search for information justifies the risks to which the subjects taking part in the clinical trial are exposed.

The clinical trial development of drugs is regulated by Royal Decree 561/1993,[15] whereas clinical trials referring to health devices are regulated by Royal Decree 414/1996.[16] Clinical trials must be authorized by the Spanish Medicine Agency with previous assessment by the ethics commitees. The ethics commitees of clinical research will be accredited by the Regional Health Authority in each autonomous community, which has to communicate with the Ministry of Health and Consumer Affairs.[14] Clinical trials will be performed respectfully in relation to fundamental human rights and ethical postulates affecting biomedical research in humans, following the contents of the declaration of Helsinki and its succesive updates.[17] It will be necessary to obtain and document informed consent, freely stated, from each subject of the study before the patient is included.

Furthermore, it is strongly recommended that investigators, sponsors, monitors, and all others involved in clinical trials adhere to international standards for the proper management of clinical trials (i.e., GCP released by the International Conference on Harmonisation, involving the European Medicines Evaluation Agency [EMEA], and the agency's counterparts in other countries [United States and Japan]).[18]

CLINICAL TRIALS AND THE CLINICAL PHARMACIST

The role of the clinical pharmacist in clinical trials is going through a remarkable expansion process. Currently, there are different ways to integrate pharmacists into the clinical research environment.[4,19,20] Among these, it is important to mention the contribution of clinical pharmacists, as staff members, to the ethics commitee of clinical research, their participation in the development of protocols by managing the dispensing and use of investigational drugs, and their direct role as investigators, reviewing protocols and performing educational activities.

According to Royal Decree 561/93 (article 41),[15] on the minimum requirements for the accreditation of an ethics commitee of clinical research, it is stated that at least one hospital pharmacist must belong necessarily to the commitee. In this way, clinical pharmacists are capable of evaluating methodological and logistical aspects of each protocol and are competent to consider the ethical issues of clinical trials.

As mentioned previously, Royal Decree 561/93 (article 18),[15] on the distribution of investigational drug samples, it is stated that pharmacy service is responsible for written acknowledgment of receipt, custody, and dispensing of the drug being evaluated. Together with this recognition are the latest guidelines for GCP.[18] The result is easy to see. Years ago the problem for the pharmacy was to take care of the investigational drug, whereas today the problem is to find resources to facilitate the work load, which includes control of the entire process, as stated by Ferrer.[22]

Although regulations do not initially consider the role of the clinical pharmacist as an investigator,[1] it has been stated that hospital pharmacists who are experienced in research are fully prepared to participate in all processes within the research environment.[23] In our understanding, sponsors are still reticent to ask the pharmacist to play the

role of investigator in clinical trials. Nevertheless, because of the pharmacist knowledge of the principles governing therapeutics, together with the intense relationship that they maintain with all the departments within the hospitals, the hospital pharmacist is a valuable asset for the design, development, review, and collaboration for preparation of the protocol, as stated before.[24]

Different surveys on the status of the role of the clinical pharmacist in clinical trials have been presented.[3,21,25] The average number of clinical trials started per year and hospital is 9.6, and there is a wide range of variation (up to 70 trials per year in large hospitals). However, the latest data indicate a dramatic increase in activity (around 100–150 trials per year). To summarize the results, it can be stated that, in 76.2% of hospitals, the pharmacy is the receiving site for investigational drugs, and 90.4% give written acknowledgment of receipt. Direct dispensing to the patient is executed in 59.5% of centers, whereas dispensing to the investigator was executed in 29.2% of hospitals.[3] Inventory control of samples for investigation is intensively observed in 85.7% of institutions. If the point of view of the industry is taken into account,[25] similar results are obtained; that is, distribution of the investigational drug is performed by the pharmacy service in 82.8% of centers. In addition, the pharmacy's role of dispensing drugs facilitates the monitor's task in 71% of cases. Interestingly, sponsors recognize that pharmacists are investigators in 12% of clinical trials, and that almost all of them (94% of sponsors) consider that the presence of pharmacist on the ethics commitee of clinical research is essential for evaluating protocols. The value of the pharmacists' activity in clinical trials is essentially not different from those obtained in surveys developed in other countries.[26]

Regarding human resources in this field, most centers manage clinical trials by assigning one or more part-time pharmacists or technicians who also work on traditional activities such as drug delivery and drug information. Therefore, it is difficult to estimate the number of protocols that can be managed by one full-time employee. Only centers developing more than 70 clinical trials per year are able to have one full-time employee dedicated for clinical research.[3] This fact is linked to another extremely important issue: The revenue for pharmacy costs is associated with research. In the current context of hospital operating costs, the structural resources and time spent by the hospital pharmacy service for clinical trial-related activities are difficult to justify. As it has been pointed out,[27] only by carefully quantifying the costs for providing this service and demonstrating that the benefits outweight the costs, can the pharmacy justify a new expansion program. In this way, a model for estimating and evaluating the cost of pharmacy activity for any given clinical trial was described. The average time spent per trial was 91 hours, the average cost per trial was $1766, and the average cost per patient was $174.[27] Although it is clear that clinical research activities should be funded by specific economic resources, this consideration is not always taken into account. Likewise, costs other than those of the investigator, such as the costs of pharmacist activities, are usually not taken into account when the total cost of a clinical trial is calculated. Even, if these costs are considered, they are fixed by people who are not familiar with the pharmacy. Consequently, the current sources for funding used to support the pharmacists' participation in clinical trials are not homogeneous, ranging from fees charged to investigators (usually reimbursed through the funds the investigator receives from the sponsor) to the covering of the costs assumed by the institution as part of the cost of participating in a research program. This picture does not differ essentially from that described by Rockwell et al. in their survey.[26]

The economic impact of drug studies on the pharmacy budget should be considered. Spanish regulations[15] give responsability to the sponsor for providing evaluated drugs free of charge. Along these lines, two reports measured the savings resulting from the development of clinical trials. In one case, 23 clinical trials saved almost 0,30 million €, during the period 1994–1996.[28] In a second study, of the 105 clinical trials conducted in our hospital during January 2000, 36 were evaluated, and the results indicated a total savings of 1,65 million €; from the rest of the studies, 55 therapies were evaluated without an established treatment, 2 were sponsored by the own hospital, and 9 added, not substituted, the investigational drug to the conventional treatment.[29] These savings are consistent with those corresponding to two pharmacy-based investigational drug services in the United States for fiscal period 1996–1997.[30]

From the institutions point of view, the Spanish Society of Hospital Pharmacy [Sociedad Española de Farmacia Hospitalaria (SEFH)] considers the clinical trials a matter of interest. As proof of this fact, there was a meeting organized in the early 1990s in which more than 50 experts described and analyzed the role of the hospital pharmacists in the growing world of clinical trials.[31] Furthermore, the reference text Farmacia Hospitalaria dedicates an entire chapter to the clinical trials issue.[32] Nevertheless, whereas different associations (e.g. American Society for Health-System Pharmacists, Joint Committee on Accreditation of Healthcare Organizations)[8] have edited guidelines oriented to establish and define the rules of the clinical pharmacist in clinical trials, the SEFH has still not taken the step. Regarding educational programs for residents, there are no standardized guidelines for rotations in investigational drug services, and each

hospital acts according to its own criterion. Moreover, the recent edition of the resident's manual[33] does not consider specifically the issue of clinical trials.

As mentioned previously, the role of the clinical pharmacist in clinical trials in Spain must be considered in three main ways: the participation in the development of protocols by managing the dispensing and drug accountability by means of the pharmacy-based investigational drug services; the contribution of the clinical pharmacist, according to its condition of permanent member, to the ethics commitee of clinical research; and the direct role as investigators, conducting clinical trials.

PHARMACY-BASED INVESTIGATIONAL DRUG SERVICES

The application of the current regulations[15] and GCP recommendations[18] leads to the constitution of the investigational drug services within the pharmacy department in medium-size and large hospitals, which are involved in the developing process of a great number of protocols. The need for a specialized area in which to manage clinical trials is widely recognized among pharmacists.[34] In addition, the investigational drug services allow hospital pharmacists to specialize in the concrete area of clinical research, which is continuously evolving. Moreover, the workload that clinical trials represent can be accurately measured in the context of pharmacy service, and strategies for figuring costs and reimbursements can be adequately carried out. In some cases, a clinical trials agency is created in an attempt to integrate all clinical procedures in the hospital setting.[35]

In our hospital (a typical third-level hospital having more than 1500 beds), more than 150 clinical trials are under development. Years ago, the pharmaceutical support unit for clinical trials was created; at the present time, it involves a clinical pharmacist and a technician, both full-time employees dedicated to clinical trials-related activity.

The main goals of the pharmacy-based investigational drug services are as follows:

- To offer sponsors, investigators, and patients a guaranteed quality in the clinical trial process, by executing a correct reception, storage, and dispensation of the investigational drug.
- To collaborate with investigators and sponsors in the design of clinical trials and their follow-up.
- To collaborate with the ethics commitee of clinical research by offering information periodically on the number of patients included in each protocol and reporting incidences considered serious for the clinical trial follow-up.

The description of the basic activities (in chronological order) are as follows:

- Reception and study of protocol

  Opening protocol file
  Checking preceptive documentation
  Protocol study
  Meetings with monitors and/or investigators
  Evaluating pharmacy participation
  Opening computerized record
  Establishing dispensing procedures
  Information activities

- Drug management

  Drug reception
  Dispensing procedure
  Storage
  Stock management
  Returned drugs management
  Returning unused drug to sponsor
  Feeding computer records of activity

- Finishing the study

  Final inventory
  Balance of drug accountability (receptioning/dispensing)
  Closing computerized record
  Meetings with monitors and/or investigators
  Closing the protocol file
  Institutional or sponsor audits

As a function of the clinical trial or the nature of the investigational drug, there are some other specific activities:

- Keep the randomization codes and opening them, if necessary
- Assigning patients to treatment groups, according to randomization tables
- Packing or acconditioning samples for suitable use and administration
- Preparing solutions or mixtures and diluting the drug for parenteral use under aseptic conditions
- Preparing or acconditioning samples that require specific handling conditions (cytotoxics, biologics, gene therapy)

- Patient information and training (especially in the case of outpatients)
- Destruction of the returned or unused drug samples through a suitable procedure
- Evaluation of the patient's and investigator's adherence to protocol

For the adequate management of the investigational samples in the context of the activity of the pharmacy, it is necessary to consider the following:

- Integrating the pharmacy-based investigational drug activity within the pharmacy service, making use of common settings and facilities
- Establishing a differentiated flow to manage samples for investigation within the pharmacy service
- Storing the investigational drugs in a specific, unique place, far from the conventional drugs
- Establishing measures to keep the samples safe and guaranteeing their integrity (i.e., locks in shelves, temperature alarms)
- Relaying on trained and specialized pharmacists and technicians, even full-time employees, if the number and complexity of clinical trials requires it
- Defining an individual and concrete prescription sheet, essential for dispensing the investigational drug
- Keeping all documents and activity records in separate files for each clinical trial
- Computerizing all the clinical trial development, using available software programs (purchased software or developed in-house systems)
- Establishing safety measures to guarantee the confidentiality of the protocol and the patients, to include protecting investigational samples, files, and computer programs
- Elaborating suitable standard operating procedures for all activities related to the clinical trial performance

It is important to define the reimbursment process for providing the investigational drug services. There are two main procedures: a fixed reimbursement per trial for traditional services and a variable reimbursement estimated per clinical trial for other services;[36] and a fee structure (fixed and variable) in which each activity involved in a clinical trial is detailed.[27,37] In our case, we use the first procedure because of its simplicity. Nevertheless, a new fee questionnaire describing the cost of each pharmacy-related activity is under evaluation.

As stated previously, a specifically defined computer program is essential for maintaining inventory control and accountability. There are different software programs available, but beside conventional databases, there are two main programs: TRIALS[38] designed by a working party of the SEFH; and the recently updated GECOS, designed in our pharmacy service.[39,40]

ETHICS COMMITEE OF CLINICAL RESEARCH

The ethics commitee of clinical research is the institutional entity at the local institution that is responsible for protecting the rights of human.[15] It plays a similar role to the institutional review board in other countries.[41] The main functions of this entity are to examinate the methodological, ethical, and regulatory issues of each protocol proposed for development in the hospital.

In detail, the commitee must evaluate, among other things, the following:

- The appropriateness of the protocol related to the aim of the study, its scientific efficiency, and the balance between the expected risks and benefits of the new therapy
- The appropriateness of the investigator and the research team responsible for developing the clinical trial within the hospital
- The informed consent document to be given to the patients, from the point of view of the respect for human rights
- The clinical trial follow-up, from the beginning of the study to the receiving of the final report

The ethics commitee is composed of members with or without a background in health care and research. At least one clinical pharmacist must be a member of the ethics commitee. According to a survey,[3] the pharmacist is president of the commitee in 4.8% of cases, secretary in 36.5% of cases, adviser in 12.1% of cases, or voting member in 46.6% of cases. Thus, it is understood that clinical pharmacists have the knowledge and the responsability to evaluate and monitor a diversity of clinical, methodological, and ethical aspects relating to clinical trials.

For this reason, it is remarkable that, in many cases, clinical pharmacists lead the follow-up process for the clinical trials. It was in a pharmacy-promoted audit that a serious deviation in GCP recommendations was detected. In this study, it was concluded that compliance was adequate in 50% of protocols, so-so in 25% of cases, and poor in the remaining 25%. Surprisingly, in 13% of the patients, the informed consent document was not signed; in 15% of the cases, the patient's clinical records did not reflect that the patients were included in a clinical trial.[42] In a different way, a long-term follow-up detected that

only 32% of clinical trials previously evaluated by the local ethics commitee was finally published at the end of the protocol. Moreover, the sponsor sent the final report of the clinical trial to the ethics commitee in only 33 of 135 finished clinical trials.[43]

The role of the clinical pharmacist in the surveillance of ethics principles and the maintenance of the rights of human can also be notorious, especially when referring to written information and the patient's informed consent.[44] The most relevant study undertaken in Spain that evaluated the quality of the written information provided to patients was carried out by pharmacists involved in quality assurance and/or ethics commitees.[45] The main outcome of this study was to confirm that most of the written information to patients (65.3% of clinical trials) required high-level studies to be completely understood by the patients. As far as we know, a more ambitious, multicentric study is currently under development on the true comprehension and awareness that patients have of the clinical trials in which they are involved.

As a whole, the pharmacist's presence in ethics commitees allows the pharmacy service to solve practical problems related to the execution of the clinical trial, prior to the approval of the protocol. Moreover, by evaluating methodological aspects of protocols, the clinical pharmacist is asked to develop future protocols, linking with pharmacist's role as clinical researcher.

THE CLINICAL PHARMACIST AS CLINICAL RESEARCHER

It is clearly understood that pharmacy services and clinical pharmacists should play an important role in clinical research.[46] In this sense, a survey noticed that a clinical pharmacist was the investigator in 12% of clinical trials.[3] Nevertheless, the percentage of protocols in which a pharmacist is integrated into the research team is higher.

In fact, it is not rare that pharmacists collaborate in activities that are not considered to be routine drug management. The pharmacists may be responsible for randomization of the patients in treatment groups. If the study is double-blind, pharmacists can calculate dosages, keeping the investigator unaware of treatment assignments. Nevertheless, the main field in which a clinical pharmacist can expand is with the institutionally sponsored research of off-label treatments. Such research may involve an existing drug product, a new formulation, a new method or route of administration, or any combination of these that is not covered by the Spanish Medicine Agency-approved labeling; as well as clinical trials that involve activities familiar to pharmacists according to their background (i.e., pharmacokinetics, pharmacoeconomics).

In the near future, within the context of our changing health care environment and research environment, there is a need for multidisciplinary approaches. The clinical pharmacist should demonstrate, according to their expertise in the principles governing therapeutics, that they are able to participate fully in this expanding process within the research environment. Thus, a hospital pharmacist would be valuable in the design, development, review, and preparation of the protocol and, finally, in evaluating and reporting results.

REFERENCES

1. *Ministerio de Sanidad y Consumo. Ensayos Clínicos en España (1982–1988)*; Monografías Técnicas: Madrid, 1990; Vol. 17.
2. Vlasses, P.H. Clinical research: Trends affecting the pharmaceutical industry and the pharmacy profession. Am. J. Health-Syst. Pharm. **1999**, *56*, 171–174.
3. Quevedo, A.; Pérez, L.; Fernández, A. Participación del farmacéutico de hospital en la investigación clínica. Farm. Hosp. **1999**, *23*, 24–41.
4. Idoate, A.; Giráldez, J.; Idoipe, A. Trials: Aplicación informática para la dispensación y control de medicamentos en fase de investigación clínica. Farm. Hosp. **1995**, *19*, 24–30.
5. Data not published. Pesonal communication. Agencia Española del Medicamento. Ministerio de Sanidad y Consumo.
6. Vázquez, J.R.; Moncín, C.; Huarte, R.; Idoipe, A.; Palomo, P.; Marco, R. Ensayos clínicos: Participación del servicio de farmacia. Farm. Clín. **1995**, *12*, 178–188.
7. Escoms, M.C.; Novoa, C.; Jódar, R.J.; Suñé, J.M. Perfil de los ensayos clinicos evaluados en un hospital general durante quince años: Utilidad de un programa informático. Farm. Clín. **1997**, *14*, 341–347.
8. Lunik, M.C. Clinical research: Managing the issues. Am. J. Health-Syst. Pharm. **1999**, *56*, 170–171.
9. Phillips, M.S. Clinical research: ASHP guidelines and future directions for pharmacists. Am. J. Health-Syst. Pharm. **1999**, *56*, 344–346.
10. Cipywnyk, D.M. A survey of pharmacy-coordinated investigational drug services. Can. J. Hosp. Pharm. **1991**, *44*, 183–188.
11. Giraldez, J.; Idoate, A.; Jimenez-Torres, N.V.; Ribas, J.; Rodríguez-Sasiain, J.M. Aspectos Prácticos de la Participación del Servicio de Farmacia en los Ensayos Clínicos del Hospital. In *Sociedad Española de Farmacia Hospitalaria. Jornadas de Actualización Sobre Ensayos Clínicos*: Madrid, 1990; 65–118.
12. American Society of Health-System Pharmacists. ASHP guidelines on clinical drug research. Am. J. Health-Syst. Pharm. **1998**, *55*, 369–376.

13. Ley 14/1986, de 25 de abril, general de sanidad. Ministerio de Sanidad y Consumo. B.O.E. no. 78, de 27 de abril de 1986.
14. Ley 25/1990, de 20 de noviembre, del medicamento. Ministerio de Sanidad y Consumo. B.O.E. no. 306, de 22 de diciembre de 1990.
15. Real Decreto 561/1993, de 16 de abril, por el que se establecen los requisitos para la realización de ensayos clínicos con medicamentos. Ministerio de Sanidad y Consumo. B.O.E. no. 114, de 13 de marzo de 1993.
16. Real Decreto 414/1996, de 1 de mayo, por el que se regulan los productos sanitarios. Ministerio de Sanidad y Consumo. B.O.E. no. 99, de 24 de abril de 1996.
17. Declaración de Helsinki: recomendaciones para orientar a los médicos en los trabajos de investigación biomédica con sujetos humanos. Adoptada por la 18ª Asamblea Médica Mundial (Tokio, Japón, octubre de 1975), por la 35ª Asamblea Médica Mundial (Venecia, Italia, 1983) y por la 41ª Asamblea Médica Mundial, Somerset West, República de Sudáfrica, octubre 1996.
18. Organización Mundial de la Salud (International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use) Good Clinical Practice: Consolidated Guideline. Documento no. E6GCPD12WP6. ICH Secretary. Ginebra, may 1996.
19. Ordovás, J.P.; Jimenez-Torres, N.V. El Servicio de Farmacia en el Àmbito de la Investigación Clínica de Medicamentos en el Hospital. In *El Ensayo Clínico Como Tarea Cooperativa*; Barlett, A., Serrano, M.A., Torrent, J., Eds.; Monografías Dr. Esteve, Fundación Dr. Esteve: Barcelona, 1992; Vol. 13; 27–35.
20. Rodilla, F.; Magraner, J.; Fuentes, M.D.; Ferriols, F. Ensayos clínicos y su repercusión en un servicio de farmacia hospitalaria. Farm. Hosp. **1994**, *18*, 249–254.
21. Sacristan, J.A.; Bolaños, E. Papel de los servicios de farmacia en la realización de ensayos clínicos: Punto de vista de la industria farmacéutica. Farm. Hosp. **1995**, *19*, 364–367.
22. Ferrer, M.I. El control de los medicamentos de ensayo clínico: Perspectivas y necesidades actuales. El Farmacéutico Hospitales **1994**, *52*, 38–39.
23. York, J.M.; Alexander, J.G.; Barone, J.A. The value of the clinical pharmacist in the drug development process. Clin. Res. Pract. Drug Regul. Aff. **1998**, *6*, 23–39.
24. Gouveia, W.A. Regulatory Authority affecting american drug trials: Role of the hospital pharmacist. Drug Inf. J. **1993**, *27*, 129–134.
25. Gallastegui, C.; Ascunce, P.; Dávila, C.; Boado, A. Servicios de farmacia y ensayos clínicos: Encuesta a la industria farmacéutica. Farm. Hosp. **1999**, *23*, 231–237.
26. Rockwell, K.; Bockheim-McGee, C.; Jones, E.; Kwon, I.W.G. Clinical research: National survey of U.S. pharmacy-based investigational drug services-1997. Am. J. Health-Syst. Pharm. **1999**, *56*, 337–344.
27. Idoate, A.; Ortega, A.; Carrera, F.J.; Aldaz, A.; Giráldez, J. Cost-evaluation model for clinical trials in a hospital pharmacy service. Pharm. World Sci. **1995**, *17*, 172–176.
28. Barroso, E.; Ferrer, M.I.; Jódar, R. Direct Economical Impact of Clinical Trials 1994–1996. In *3rd Congress of the European Association Hospital Pharmacists*; Edimburgh: UK, 1998.
29. Valdés, G.; Suñé, M.P.; Montoro, J.B. Impacto económico de los ensayos clínicos en un hospital general: Ahorro en costes farmacéuticos. Farm. Hosp. **2000**, *24*, 93–94, (Esp. Congr.).
30. McDonagh, M.S.; Miller, S.A.; Naden, E. Costs and savings of investigational drug services. Am. J. Health-Syst. Pharm. **2000**, *57*, 40–43.
31. *Sociedad Española de Farmacia Hospitalaria. Jornadas de Actualización Sobre Ensayos Clínicos*: Madrid, 1990; 300 pp.
32. Idoate, A.J.; Caínzos, M.D.; Idoipe, A. Ensayos Clínicos. In *Farmacia Hospitalaria*; Bonal, J., Domínguez-Gil, A., Eds.; Editorial Médica Internacional SA: Madrid, 1993; 645–691.
33. Bermejo, T.; Cuña, B.; Napal, V.; Valverde, E. *Manual del Residente de Farmacia Hospitalaria*; Sociedad Española de Farmacia Hospitalaria, 1999; 917 pp.
34. Jódar, R. Los ensayos clinicos constituyen una sección con personalidad propia en el Servicio de Farmacia (entrevista). El Farmacéutico Hospitales **1994**, *52*, 6–8.
35. Gómez, B.; Codina, C.; Ribas, J. In *Clinical Trials Agency*, ASHP Annual Meeting, Orlando, Florida, 1999, poster presentation, Intl-51.
36. Swartz, A.J. Reimbursement for involvement in investigational drug protocols. Am. J. Hosp. Pharm. **1989**, *46*, 1334.
37. Anandan, J.V.; Isopi, M.J.; Warren, A.J. Fee structure for investigational drug studies. Am. J. Hosp. Pharm. **1993**, *50*, 2339–2343.
38. Idoate, A.; Giráldez, J.; Idoipe, A.; Garrido-Lestache, S. Trials®:Aplicación informática para dispensación y control de medicamentos en investigación clínica. Farm. Hosp. **1995**, *19*, 24–30.
39. *Gecos v1.1. Programa Multiusuario de Gestión de Ensayos Clínicos Desarrollado para Servicios de Farmacia Hospitalaria*; Grifols SA: Barcelona, Spain, 2000.
40. Oliveras, J.; Jódar, R.J.; Suñé, J.M. Programa informático aplicado al control de ensayos clínicos. Farm. Hosp. **1990**, *14*, 83–87.
41. Wermelling, D.P. Clinical research: Regulatory issues. Am. J. Health-Syst. Pharm. **1999**, *56*, 252–256.
42. De la Llama, F.; Gutierrez, P. Auditoría sobre ensayos clínicos. Farm. Hosp. **1996**, *20*, 114–117.
43. Monzó, M.; Pla, R. Seguimiento de los ensayos clínicos finalizados y sus posteriores publicaciones. Farm. Hosp. **2000**, *24*, 107–108, (Esp. Congr.).
44. Ordovás, J.P. Consentimiento informado del paciente en los ensayos clínicos (editorial). Farm. Hosp. **1999**, *23*, 267–270.
45. Ordovás, J.P.; López, E.; Urbieta, E.; Torregrosa, R.; Jiménez-Torres, N.V. Análisis de las hojas de información al paciente para la obtención de su consentimiento informado en ensayos clínicos. Med. Clín. (Barc.) **1999**, *112*, 90–94.
46. Ordovás, J.P. Investigación clínica en España y servicios de farmacia hospitalaria. Farm. Hosp. **1996**, *20*, 189–191.

Society of Hospital Pharmacists of Australia, The

Naomi Burgess
Society of Hospital Pharmacists of Australia, South Melbourne, Australia

INTRODUCTION

The Society of Hospital Pharmacists of Australia (SHPA) is the professional body that represents pharmacists practicing in hospitals and similar institutions throughout Australia.

Established in 1941, the Society has a long-standing commitment to the profession of hospital pharmacy and to its role in ensuring optimal health outcomes for Australians. Fundamental to its success is the Society's culture of cooperation and contribution, which is reflected in the high level of membership involvement.

In November 1999, SHPA members voted in a new Constitution based upon revised Memorandum and Articles of Association, developed to incorporate changes in Corporation Law and to ensure that SHPA keeps abreast of professional, technology, and social changes.

New membership categories were introduced as a consequence of the new Constitution. Membership has now expanded to include pharmacy technicians, inactive members, and overseas members.

ORGANIZATIONAL STRUCTURE AND GOVERNANCE

SHPA is governed by a Federal Council which is supported by a divisional structure. There also local Branch Committees in each State and Councilors are elected by these Committees to represent the States at the federal level. All Councilors, Branch representatives, and Division/Committee members work in a voluntary capacity.

Federal Council (As of 1 March 2001)

Executive

Helen Dowling, Federal President
Naomi Burgess, Federal Vice President
Helen Matthews, Federal Treasurer
Sue Kirsa

Federal councilors

Neil Keen
George Taylor
Christine Maclean
Andrew Matthews
Paul Muir

Executive director

Yvonne Allinson

The Federal Secretariat plays a critical role in serving the needs of members and in supporting the activities of the Society. It is based in the Society's offices in Melbourne, Victoria, Australia.

The Divisions and Committees, which report to the Federal Council, develop and implement policy in the areas central to SHPA's goals. They include the Publications Division; Research, Grants and Development Committee; Division of Specialty Practice; Liaison and Promotion Unit, and the Division of Education. Each is responsible for advising the Federal Executive of new developments and opportunities that will allow SHPA to continue its mission of promoting and developing the practice of pharmacy in hospitals and other healthcare settings.

There are 15 Committees of Speciality Practice, which reflect a wide range of professional interests and are responsible for contributing to the professional development of SHPA members as well as maintaining and enhancing standards throughout hospital pharmacy practice.

MEMBERSHIP

SHPA currently represents over 1,500 pharmacists and pharmacy technicians working in hospitals and related institutions. This represents over 80% of Australian hospital pharmacists.

DOI: 10.1081/E-ECP 120006304

MISSION AND KEY OBJECTIVES OF SHPA

Mission Statement

SHPA is committed to promoting the quality use of medicines through the ongoing development, application, and implementation of leading-edge pharmacy practice in hospitals and other healthcare organizations.

Goals

- To increase the status, influence, and profile of the profession of hospital pharmacy.
- To provide appropriate services to SHPA members.
- To expand the career opportunities for members of SHPA.
- To foster strong and positive corporate unity within SHPA.
- To generate resources to maintain and expand SHPA activities and to facilitate research.
- To establish and promulgate standards and guidelines in all relevant areas of pharmacy practice.
- To ensure the availability and accessibility of comprehensive, relevant education.
- To develop an effective network between SHPA and other relevant organizations.
- To provide appropriate services to organizations and individuals external to the membership.

MEMBER BENEFITS

Members have access to a range of services and programs aimed at enhancing professional standards and contributing to the ongoing development of hospital pharmacy practice. These include:

The Australian Journal of Hospital Pharmacy

This renowned publication provides a forum for the exchange of knowledge and ideas about new initiatives and developments in hospital pharmacy. It publishes the research of new and established authors.

Publications and Textbooks

SHPA publishes an impressive range of publications including:

- SHPA Practice Standards and Definitions.[1]
- Australian Injectable Drugs Handbook.[2]
- Clinical Pharmacy—A Practical Approach.[3]
- Australian Drug Information Procedure Manual.[4]
- Drug Usage Evaluation—Starter Kit.[5]
- Directory of Hospital Pharmacy and Pharmaceutical Organisations.[6]

SHPA Bulletin and Branch Newsletters

These newsletters keep members up-to-date with news and views at a national and local state level.

Education Programs

SHPA co-ordinates a comprehensive range of education services for its members and other pharmacists and healthcare workers interested in pharmacy and medication use. Continuing Professional Development is delivered throughout Australia, with branches in each state facilitating regular meetings on topical issues. SHPA works in conjunction with universities to deliver postgraduate diplomas designed to give hospital pharmacists the skills for pharmacy leadership. Postgraduate studies are recognized by SHPA through the Society's Fellowship program.

Research, Development, and Grants

SHPA administers a grants program aimed at supporting research and development in the practice of hospital pharmacy. During 1999, 103 grants were awarded with just under A$140,000 being distributed. SHPA also actively supports research and development by commissioning studies in areas of major importance to the profession including the impact of clinical pharmacy services[7,8] and casemixbased funding and management for hospital pharmacy.[9,10]

Advocacy

A key role of SHPA is advocacy for the profession and its expanding role in provision of quality healthcare services. SHPA represents the members, at both state and national levels, on many important issues in relation to public health policy, funding, and education.

CURRENT INITIATIVES AND FUTURE DIRECTIONS

The recently completed Clinical Pharmacy Intervention Study[8] was commissioned by SHPA to quantify the benefits of clinical pharmacist's interventions. Eight teach-

ing hospitals were involved in the study, the first multisite cost-benefit analysis of clinical pharmacy interventions in Australia. The results showed that over A$4 million per annum were saved by the hospitals because of the direct intervention of clinical pharmacists in drug treatments. The study will form a key component of a campaign to increase awareness of the important role hospital pharmacists have in ensuring safe, high quality, and cost-effective healthcare and of maintaining adequate levels of clinical pharmacy services.

With the rapidly aging Australian population in mind, SHPA signed an agreement with the internationally recognized Commission for Certification in Geriatric Pharmacy in 2000. The agreement sees the two organizations teaming up to offer the first examination-based competency assessment for Australian pharmacists. SHPA has negotiated with the Australian Government for CCGP-credentialed pharmacists to access funding for clinical services provided to patients in both hospitals and community settings.

Provision of quality educational services in pharmacy and related areas is one of the core businesses of SHPA and an area of ongoing expansion and development. In recent times, the focus of these services has broadened from predominantly addressing the needs of hospital pharmacists, to incorporating nursing and community pharmacist education. With the inclusion of pharmacy technicians in our membership starting in 2000, educational needs of this group will be more formally addressed.

SHPA's most recent strategic planning cycle began in February 2001.

MAJOR MEETINGS

Biennial Clinical Pharmacy Conference

October 2000: Gold Coast, Queensland
October 2002: Sydney, New South Wales

Biennial Federal Conference

November 2001: Hobart, Tasmania
November 2003: Canberra, Australian Capital Territory

SHPA State Branch Conferences

These meetings are annual or biennial, usually held in alternating years with Biennial Federal Conference.

Annual general meeting

November 2001: Hobart, Tasmania

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REFERENCES

1. *Practice Standards and Definitions*; Johnstone, J.M., Vienet, M.D., Eds.; The Society of Hospital Pharmacists of Australia: Melbourne, Australia, 1996, ISBN 0 9588944 9 3.
2. *Australian Injectable Drugs Handbook*, 2nd Ed.; Morris, N., Ed.; The Society of Hospital Pharmacists of Australia: South Melbourne, Australia, 1999, ISBN 0 9586881 17.
3. *Clinical Pharmacy—A Practical Approach*; Hughes, J., Donnelly, R., James-Chatgilaou, Eds.; Macmillan Education Australia Pty Ltd.: South Yarra, Australia, 1998, ISBN 0 7329 4719 7.
4. *Australian Drug Information Procedure Manual*; Foran, S., Ed.; The Society of Hospital Pharmacists of Australia: South Melbourne, Australia, 1996.
5. *Australian Drug Usage Evaluation Starter Kit*; SHPA Drug Usage Evaluation Committee of Specialty Practice, Ed.; The Society of Hospital Pharmacists of Australia: South Melbourne, Australia, 1998.
6. *Directory of Hospital Pharmacy and Pharmaceutical Organisations*; Vernon, G., Thomson, W.A., Eds.; The Society of Hospital Pharmacists of Australia: South Melbourne, Australia, 2001.
7. Allen, K.M.; Dooley, M.J.; Doecke, C.J.; Galbraith, K.J.; Taylor, G.R.; Bright, J.; Carey, D.L. A prospective multicentre study of pharmacist initiated changes to drug therapy and patient management in acute care government funded hospitals, *in press*.
8. Dooley, M.J.; McLennan, D.N.; Galbraith, K.J.; Burgess, N.G. Multicentre pilot study of a standard approach to document clinical pharmacy activity. Aust. J. Hosp. Pharm. **2000**, *30* (4), 150–157.
9. Burgess, N. *The National Pharmacy Casemix Bridging Study—Report to the Commonwealth Department of Health and Family Services*; The Society of Hospital Pharmacists of Australia: Adelaide, Australia, 1998.
10. Howitt, K.; Burgess, N.; Brooks, C. *The Refinement and Application of PharmGroup Classifications as a Management Tool for Competitive Neutrality in the Health Industry*; Report to The Society of Hospital Pharmacists of Australia: Melbourne, Australia, December 2000.

PROFESSIONAL ORGANIZATIONS

Spanish Society of Hospital Pharmacy

Ma. Isabel Crespo Gonzalez
Urbanización Monteclaro, Madrid, Spain

INTRODUCTION

The Spanish Society of Hospital Pharmacy (SSHP) is the only national association of its kind to group together hospital pharmacists in Spain. The society is very well established within the profession due to its long tradition of protecting the interests of the sector. It has not always been easy to maintain the importance and representative of the society. However, due to the efforts of its presidents and the pharmacists themselves, it is now one of the most relevant hospital pharmacy societies in Spain and in Europe.

BACKGROUND

The growth of the society is directly related to the incorporation of newly trained specialists who tend to join the society once they have completed their studies and participate in the development of new work groups. This coupled with the experience and scientific knowledge of the older members makes the SSHP one of the most advanced hospital pharmacy societies in Europe. For more information about this organization, please visit our web site at www.sefh.es.

With targets very similar to its present-day objectives and members drawn from pharmacists working for charity, healthcare, and social service institutions, the Asociación Nacional de Farmacéuticos de Hospitales Civiles (National Civil Hospital Pharmacy Association) was founded in Madrid in 1955. The promotion of the hospital pharmacist's scientific, technical, and teaching activities and, in general, of all issues relating to health system pharmacy, remains enshrined in the bylaws today. After changing its name to Asociación Española de Farmaćeuticas Hospitalarios (the Spanish Hospital Pharmacists Association), the original association finally became the Sociedad Española de Farmacia Hospitalaria (the Spanish Society of Hospital Pharmacists) in 1988.

Two landmarks in particular are closely linked to the development of hospital pharmacy in Spain. The first was the official recognition of the speciality; the second, the creation of the Comisión Nacional de la Especialidad Española de Farmacia Hospitalaria (National Commission for the Spanish Hospital Pharmacy Speciality), on which the SSHP is represented. These two developments led to the first Specialists in Hospital Pharmacy qualifications being awarded in 1986.

In 1988, the foundations were laid for the modernization of the structure of what was then the association, with the creation of a Madrid-based General Technical Secretariat. The General Technical Secretariat rapidly became integrated into the new structure, which was definitively introduced in 1992, after the relevant changes to the bylaws, and under which the society's activities were separated into a number of well-defined areas. Projects currently in progress could then be included in, for instance, the economic, educational, publishing, or institutional relations areas. Projects such as Pharmacovigilance, GRDs, DDDs, and Information on Medicines and Drugs were among the priority concerns.

Below is a list of the commissions and task forces set up over the years. These bodies generate specific projects on issues and subjects on which to focus within their areas:

(Therapeutic Evaluation Commission)
Comisión de Bioética (Bioethics Commission)
Comisión de Nutrición Artificial (Artificial Nutrition Commission)
Comisión de Normas de Procedimientos (Procedure Regulations Commission)
Grupo Español de Farmacia Pediátrica (Spanish Paediatric Pharmacy Task Force)
Comité de Acreditación (Accreditation Committee)
Grupo de Estudio de Utilización de Medicamentos (Drug Use Task Force)
Grupo de Trabajo sobre GRDs (GRD Task Force)

In line with the spirit of the bylaws, particular emphasis was placed on the areas of education and publications. In fact, so much work was done in these two areas that, in 1995, they were moved to a separate

Encyclopedia of Clinical Pharmacy
DOI: 10.1081/E-ECP 120006380

new headquarters also in Madrid and more suited to their requirements.

Created in 1997, the Fundación Española de Farmacia Hospitalaria (Spanish Foundation for Hospital Pharmacy) is also closely linked to the SSHP.

Over the years, the SSHP has given top priority to its educational and publications areas. With regard to the educational area, this special interest has resulted in a substantial number of courses, grants, prizes, and aids to research. Efforts have been made to diversify so that courses oriented toward residents have coexisted alongside others directed toward the staff, in an attempt to cover the needs and requirements of the whole group.

Substantial aids are also available to ensure research projects lead to complete, fully defined developments in highly contemporary areas and subjects, often achieved by multidisciplinary and multicentric teams chosen with a view to encouraging scientific and professional exchanges. Aid is also available to outstanding young trainees, giving them access to specific knowledge in other countries in lines of work that may or may not be directly linked with our areas, but that are certain to provide a wealth of new knowledge that can then be passed on to the group as a whole.

Among the more than 130 publications issued by the SSHP's publications area are a series of regularly revised and updated monographs, general compendia, and regular journal publications. The most outstanding of these is undoubtedly the SSHP journal *Farmacia Hospitalaria* (*Hospital Pharmacy*), which, over 20 years or so, has provided a platform for some of the major landmarks in the group's story, collaborating closely in diffusion and the training of Spanish and foreign professionals. The *SSHP Information Bulletin* is another regular publication that has also accompanied us in our efforts.

Activities undertaken by the area of institutional relations intensified in 1988, after the society's 1987 entry as full member in the European Association of Hospital Pharmacists, to which it had previously belonged as an associate member. This was then accompanied by a series of agreements with our institutions, including the 1989 Pharmacovigilance Agreement, the approval given in 1993 of the SSHP's Narcotics Computer Control Programme, and the more recent official blessing for the calculation of specific pharmacy weights in GRD, and the Spanish Medicines Agency itself, with which we have collaborated in a wide-ranging series of task forces in our acknowledged role as experts in medicine and drugs.

Fully aware of this role, the society promotes and develops a range of studies, reports, and projects over a range of contemporary and future health issues via the foundation of the same name.

Finally, a brief mention of our annual Congress (first held in Madrid in 1955) is in order. The Congress has accompanied and evolved together with the society itself. This year we held the 45th Congress, the latest in a virtually uninterrupted series that provides a meeting place for Spanish hospital pharmacists and that has now become a highlight on the international health care circuit. This year, the 47th meeting of Congress is to take place in Barcelona from October 1 to October 4 2002.

Besides the Congress, approximately 20 zoned scientific meetings are held every year, although the venues for the coming year have not yet been decided. These events keep the society alive and have helped it to grow from the 50 or so associates who attended the first General Meeting in 1955 to the current membership of 1850.

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CONCLUSION

Due to its long existence and experience, the SSHP now has a very well-developed structure and is considered as a solid reference within the health field. The society has eight commissions, work groups, and task forces, more than 130 publications, a bimonthly scientific journal, an information bulletin, and educational activities (prizes, courses, grants). This and the high degree of membership among the pharmacist's professionals make this society an important and representative organization within the medical field.

BIBLIOGRAPHY

Boletín Informativo Extraordinario. Memoria 1991–1999; Sociedad Española de Farmacia Hospitalaria, 1999.
Historia de la Sociedad Española de Farmacia Hospitalaria. Tomo I; Sociedad Española de Farmacia Hospitalaria, 1995.
Historia de la Sociedad Española de Farmacia Hospitalaria. Tomo II; Sociedad Española de Farmacia Hospitalaria, 1995.
Sociedad Española de Farmacia Hospitalaria. *Anuario*; Meditex, 1997.