A German initiative towards more patient safety in oral anticancer therapy

Fewer visits to the oncologist, self-administration and storage in the patient's home: with oral chemotherapy on the rise, community pharmacists have an increasingly important role in counselling patients about anticancer therapy.

At one time, the treatment of chronic myeloid leukaemia was a complicated, time-consuming parenteral therapy with interferon, and offered little hope of sustained survival. Then came the discovery and market availability of imatinib in 2001, which fundamentally changed the treatment of chronic myeloid leukaemia; now,

treatment can be managed conveniently with tablets by the patient at home, and nearly nine out of ten patients treated with imatinib go on to live for at least 5 more years [1].

The number of oral anticancer agents has grown continuously since then. Today, about one-half of all newly developed anticancer drugs are available orally [2]. Patients appreciate the ease of handling, increased independence from medical facilities and being reminded less of their disease [3].

The main disadvantage of oral anticancer therapy is patient adherence; patients need to be willing to take their medication and capable of doing so exactly as prescribed by the oncologist. Parenteral and oral therapy require different amounts of will and capability: the tablets and capsules must be swallowed regularly and precisely in the right dose in spite of the nausea and emesis, and the severe skin reactions that may occur as side effects as described in the package inserts, or experienced as real adverse drug reactions. Also, most treatment regimens are complex, with specific time intervals between administration and meals and alternating days of therapy and days of pause. Therefore, counselling and comprehensive explanations about the benefit, risks and singular traits of oral anticancer therapy are pivotal for the empowerment of patients in oral anticancer therapy.

In an article addressing adherence in tumour therapy, US health services researchers concluded that visits to the medical oncology facility will be insufficient to ensure adherence to oral anticancer agents [1].

In countries in which oral anticancer drugs are dispensed by community pharmacies, direct contact between the patient and the pharmacist at the point of dispensing the prescribed drugs offers the patient pharmaceutical advice that complements and affirms the advice of the physician. This opportunity should not be missed.



prepared in specialized pharmacies equipped with the technology to ensure safe and sterile handling of the materials. Naturally, these pharmacies are more concerned with, and are, on average, more knowledgeable in the field of anticancer therapy than regular pharmacies, given the fact that antineoplastic chemotherapy is a widely neglected topic within the curriculum of undergraduate pharmacy programmes and needs to be covered by (voluntary) postgraduate education. Therefore, pharmaceutical staff in these specialized com-

In Germany, parenteral cytostatic infusions are

munity pharmacies may expect to be better prepared to counsel patients in oral therapy than non-specialized community pharmacies. Oral anticancer drugs, however, are dispensed routinely by community pharmacies in Germany, whether they are specialized or not. The important question, therefore, is where do patients go to obtain their prescriptions for oral anticancer drugs and what do they expect from the dispensing pharmacy?

In a written and anonymous opinion survey of patients undergoing oral chemotherapy carried out by the German Society for Oncology Pharmacy (*Deutsche Gesellschaft für Onkologische Pharmazie*, DGOP), patients were questioned about their latest 'dispensing event'. A total of 427 patients from 31 community pharmacies throughout Germany participated in the survey. Seventy-four per cent of patients returned their questionnaires. Patients were asked about the kind of dispensing pharmacy visited, the counselling received, both in general and specifically about the anticancer drug, specific information desired, and satisfaction with the consultation. Most participants were aged between 65 and 74 years, 53% were female, and 84% held a statutory health insurance. Four out of five patients (83%) always received their medications, including oral chemotherapy, from the same community pharmacy.

For 70% of patients, the main criterion for the selection of this one pharmacy was accessibility. Only 27% of patients filled their prescriptions from a pharmacy specialized in cancer treatment; the remaining patients selected a non-specialized community pharmacy. Over one-third of all patients did not receive any advice about their oral anticancer therapy, although about one-half of these patients would have welcomed such advice, especially about side effects, diet and complementary, and alternative treatment options. As the number of participating pharmacies was low, and as patients were recruited via the pharmacy, a selection bias and overestimation of aspects such as the percentage of counselled patients cannot be ruled out.

Strengths of the study were the anonymity of the interview and the design as a real-life observational survey. The results of this opinion survey confirm that all community pharmacies must be able to offer competent pharmaceutical advice to cancer patients to ensure patient safety. Consequently, knowledge, skills and supporting tools need to be present in every single pharmacy.

Aspects to be included in the consultation with the patient

Patients will only be adherent if they are fully convinced of the benefit of their oral anticancer therapy. In addition to prolonged survival, this may also be improved quality of life. Some patients have incorrect notions about their anticancer tablets; for example, that they are less effective, less toxic than an infusion, or both, or that their treatment regimen is just the 'last try' before palliative treatment. Other patients feel isolated because they are left to deal with their medication alone and visit the oncologist infrequently, or feel like guinea pigs trying new agents [4]. Such misconceptions should be identified by questions such as 'How do you feel with your therapy?', and corrected as quickly as possible because they are a threat to adherence.

Further topics that should be included in counselling to ensure patient safety are presented in Table 1.

Initiative 'Oral Anticancer Therapy – Safe and Effective'

The DGOP is offering nationwide support for community pharmacists who engage in counselling patients in oral anticancer therapies. To this end, the society launched the initiative 'Oral Anticancer Therapy – Safe and Effective' towards the end of 2011 together with the German Cancer Society (*Deutsche Krebsgesellschaft*).

Elements of this initiative are practice-oriented training programmes run by committed and experienced speakers throughout the country and an online database that enables quick access to the essential drug information about orally available anticancer drugs required for the pharmaceutical counselling.

Table 1: Issues that should be included in patient counselling to ensure treatment adherence

Dharmagartical agreets	Clinical agreets
Pharmaceutical aspects	Clinical aspects
Medication regimen	Drug-drug and drug-diet interactions
Drug handling	Adverse drug reactions and their prevention
What to do when administration of tablets is missed or doubled	Verification of the prescribed dosage
Special precautions (e.g. slowing of reactions, contraception and sun screen)	Check for absence of contraindications

The training programmes are based on a curriculum and designed for a contact time of 8 hours altogether. The curriculum is subdivided into three parts: basics of cancer therapy (2 hours), applied oncology pharmacy (4.5 hours) and handling of oral anticancer drugs (1.5 hours).

Part I, basics of cancer therapy, covers terminology, epidemiology, tumour development and principles of cancer therapy. Part II, applied oncology pharmacy, addresses methods of dosage individualization, side effects and their prevention as well as interactions. Part III, handling of oral anticancer drugs, explains aspects of storage, administration via enteral tubes, handling of excreted materials, disposal of waste and cleaning.

Slide sets, created by experts from within the DGOP, that ensure uniformly practice-oriented contents are available for speakers at their convenience. Currently, there are about 50 speakers prepared to offer the training units.

Training is also offered at scientific meetings, such as the well-known 'Northern German Cytostatics Workshop' (Norddeutscher Zytostatika Workshop, NZW). In September 2015, the 'NZW Sued' will be flanked by the second meeting on oral anticancer therapy in Munich. The lectures and workshop are specifically designed for the community pharmacist and will offer both an introduction to, and reinforcement of, knowledge and skills in this important field. Topics include adherence, adverse drug effects, their management, medication safety, as well as working in the inter-professional team and the limits of pharmaceutical counselling. In addition to these lectures, workshops are offered in which theoretical aspects relevant to pharmaceutical counselling are actively transferred to case-based problems. The language of the meeting is German. Further information can be found at www. orale-krebstherapie.de

In Germany, the pharmaceutical support system (PoB-DGOP, *Pharmazeutisch-onkologisches Betreuungstool der DGOP*) is a database that provides pharmacists with a quick overview of the elemental drug information for each agent, based on drug monographs available for oral anticancer agents. Moreover, it creates concise medication administration plans, diary-like tables patients can use to document their daily condition, individualized information leaflets for the patients and clinical information for their oncologists. It also stores relevant patient pharmaceutical data and facilitates documentation of the counselling process. The monographs are updated on a regular basis by pharmacists who have taken over responsibility as a drug monograph manager. Registration and use of the database are free of charge and available exclusively to pharmacists.

A network of pharmacists, oncologists and physicians of other medical specialties, as well as nurses, are needed to ensure the safety of patients in oral chemotherapies and to increase their quality of life. As pharmaceutical competence is essential in this endeavour, one of the most important challenges is



the nationwide training of pharmaceutical staff in community pharmacies and the provision of adequate tools that support oncology pharmacy practice.

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