Summary: Most of the novel targeted anticancer agents share classical characteristics that define drugs as candidates for blood concentration monitoring: long-term therapy; high interindividual but restricted intraindividual variability; significant drug–drug and drug–food interactions; correlations between concentration and efficacy/toxicity with rather narrow therapeutic index; reversibility of effects; and absence of early markers of response. Surprisingly though, therapeutic concentration monitoring has received little attention for these drugs despite reiterated suggestions from clinical pharmacologists. Several issues explain the lack of clinical research and development in this field: global tradition of empiricism regarding treatment monitoring, lack of formal conceptual framework, ethical difficulties in the elaboration of controlled clinical trials, disregard from both drug manufacturers and public funders, limited encouragement from regulatory authorities, and practical hurdles making dosage adjustment based on concentration monitoring a difficult task for prescribers. However, new technologies are soon to help us overcome these obstacles, with the advent of miniaturized measurement devices able to quantify circulating drug concentrations at the point-of-care, to evaluate their plausibility given actual dosage and sampling time, to determine their appropriateness with reference to therapeutic targets, and to advise on suitable dosage adjustment. Such evolutions could bring conceptual changes into the clinical development of drugs such as anticancer agents, while increasing the therapeutic impact of population PK-PD studies and systematic reviews. Research efforts in that direction from the clinical pharmacology community will be essential for patients to receive the greatest benefits and the least harm from new anticancer treatments. The example of imatinib, the first commercialized tyrosine kinase inhibitor, will be outlined to illustrate a potential research agenda for the rational development of therapeutic concentration monitoring.

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ADVANCES IN GENOMICS OF BLOOD PRESSURE—TIME FOR TRANSLATION
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Summary: In 2025, there will be 1.56 billion people worldwide with hypertension. Although evidence-based interventions have transformed blood pressure control, public health data show there is still poor blood pressure control, and new therapies are still needed. Paradoxically, more sophisticated understanding of pathogenesis coincides with a decline in licensing of new medicines for hypertension. Using discoveries from genomics of blood pressure could be used to select and validate drug targets, combining expertise in this area with model organism phenotyping, experimental medicine, and pharmacology alongside medicinal chemistry may assist. To reduce the cost, we could utilize the untapped potential of the electronic health record for clinical trial delivery, and “real-world” evaluation of clinical effectiveness could reduce some of the risks and costs of clinical development, allowing a new generation of molecules to be generated in an affordable manner.

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ELECTRONIC SOLUTIONS TO SAFER HOSPITAL PRESCRIBING
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Summary: Routine clinical care in hospitals has become more reliant on digital technologies over the last decade. There are now a wide variety of electronic solutions aimed at improving patient safety and optimizing the use of medicines. This focused session will describe technologies available at key stages in the prescribing process: the decision to prescribe, the prescription generation, and the ongoing monitoring of therapy.

To support the decision-making process, prescribing information is available in many different point-of-care digital solutions across various platforms such as online computerized guidelines and smartphone applications. However, there is often overwhelming information available to prescribers. Clinical decision support (CDS) tools can help because they allow more relevant information, often specific for the patient, to be embedded in the clinical workflow. Better still is the use of electronic prescribing medication administration (EPMA) systems either as standalone systems or as part of a wider electronic patient record. Such systems may influence prescribing decisions; for example, by promoting efficacious and cost-effective therapy. Other steps in the medicines use process can also be targeted by novel technologies such as automated dispensing systems and positive patient identification through barcode medication administration systems. Electronic medication administration records enable the precise monitoring of medication use on an individual patient surveillance level through to providing data for hospital-wide medication management strategies.

Individually, all of these have been shown to effect safe prescribing. The advantage of combining these technological advances—which are already available in a limited number of integrated systems—cannot be underestimated and will become increasingly important to support tomorrow’s prescribers in providing optimal patient care.

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HOW TO GOVERN A SELF-POWERED PATIENT: PRIVACY AND BIOPOWER
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Summary: A range of new technologies is about to enable patients to produce a steady flow of information about their bodies: for example, heartbeat, blood pressure, sugar level, calories spent, temperature, sleep pattern. They are seen as useful to improve the quality of life and the accuracy of treatment for many patients, especially those with chronic diseases. This is probably the case when data are collected and analyzed by professionals. But since patients (or persons not suffering from any disease) will also be to monitor their own data without immediate supervision, there is a risk of misuse and getting lost, that can lead to false or dangerous “homemade” medicine. Also, privacy of patients may be in danger. This is not only about preventing unauthorized persons from accessing these sets of very sensitive data, but probably to protect patients against themselves. Indeed, as some of them already post their genetic pattern on social networks, disclosing one’s own body’s parameter can potentially become a common practice. That would be extremely profitable for drug companies to sell their products, for example, or for insurance companies looking to filter good risks from bad ones. The lesson to be learned is that one should not consider that the data are available for any purpose just because the person decided to make his or her own data public, something that nobody will be ever able to forbid. Unfortunately, current data protection policies still consider data made public as... public. In fact, even a perfect protection of privacy could not address the problems of a complex relationship between information and power. To shed light on this subtle relationship, I will use the Michel Foucault’s concept of “biopower.” It will reveal that the project of developing techniques to build self-powered patients
creates new forms of power with specific characteristics: the need of transparent subjects, the participation of patients to the power that aims to take control on their own body, and the growing porosity between the private and public sectors. First applied to the analysis of sexuality, the concept of biopower is nowadays highly relevant to analyze this new turn in medicine practices that involve the full cooperation and transparency of patients.

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MULTIPLE SCLEROSIS—NEW CHANCES?
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Summary: The treatment of multiple sclerosis as an autoimmune disorder has benefited for several years from the progresses of biotherapeutics. Since the mid-1990s, interferon beta has been proposed as a valuable treatment for certain MS patients due to its immunomodulator properties, followed shortly after by the registration of the polypeptide glatiramer acetate. More recently, monoclonal antibodies have been developed to target selective components of the immune response and provide a selective immunosuppression that could treat the disease with an acceptable safety profile. Natalizumab was the first of these monoclonal antibodies, and other monoclonal antibodies such as rituximab or alemtuzumab, originally developed in oncology, have since been repositioned for autoimmune disorders such as MS. However, these molecules, which are very selective in their targets, often do not appear so favorable during development, and their safety profile could significantly limit their use. More recently, the development of monoclonal antibodies has refocused more on targeting proteins that play critical roles in the pathophysiology of MS, notably on the specific processes of neurotoxicity: these antibodies are now in early clinical development and may bring new avenues in the treatment of MS.

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SAFETY INFORMATION TODAY AND HOW CAN WE IMPROVE TOMORROW?
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Summary: Ever since “modern” pharmacovigilance started in the early 1980s, it has gone through changes of various pace introduced by new concepts (eg, CIOMS I-V), development of science and methodologies (eg, pharmacoepidemiology), technology (eg, databases), or regulatory requirements (eg, risk management, new legislation). Over the period of time, methods of data collection and analysis became easier, which is helpful, taking into account the fast-growing world’s population. However, everyday general medical practice did not change much despite great progress in sciences. Large safety data are accessible from organized databases in regulatory bodies, industry, medical insurance, and other organizations, facilitating their analysis and aggregate evaluation, but in many situations, actions are still triggered by the assessment of causal associations based on medical judgment performed on individual cases or case reports. The future of pharmacovigilance should be based on well-thought-through risk management combined with risk minimization activities, which will reflect preceding appropriate benefit/risk assessment. This can be delivered by adequate training in clinical pharmacology, which will include good prescribing practices and the development of regulatory science either within clinical pharmacology or as a separate discipline. In addition, the broad understanding of important safety information collected and assessed from population data and in large databases should grow and facilitate data-driven scientific decision making.

Clinical pharmacology has an important role at present and in the future by providing curricula for HCPs across the world, teaching appropriate prescribing, risk management/minimization concepts, and contributing to the increase in protection of public health and individual patient safety by being much more prominent in the HCP training and clinical practice.

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THE POISONS CENTRES NETWORKS—TOXICOSURVEILLANCE
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Summary: Every day, European poisons centers (PC) assess poisoning risks of thousands of exposures to toxic agents and give advice for best-practice medical treatment, triggered by telephone calls from medical staff, patients, or caregivers. PC are continuously registering all exposure cases in local databases and are analyzing these data to detect or verify unusual poisoning events (often involving several or many patients) and trends of poisoning.

By this method of toxicovigilance, for example, the Swiss PC detected series of unexpected breathing disorders caused by regular intended use of 1 of 3 waterproofing spray products in 2003 and, more recently in 2012, the GIZ-Nord Poisons Centre in Germany discovered a Ciguatera poisoning series (14 patients) generated by contaminated seafood (Red Snapper) purchased in local supermarkets. In some of these events, the toxic products identified were removed from shops within hours, after notifications of PCs to retail, competent regional, or national authorities, prevented many more poisonings.

In the past, unexpected poisoning risks that might have been caused by rare exposures and very rare notification to PC may have been missed if only single cases were notified to PC, and the cases could not be validated with sufficient quality. Today, networks of PC facilitate exchange of observations, case reports, and related toxicologic knowledge to rapidly confirm new or unusual poisoning risks. With help of conveniently new communication tools, several PC networks have been founded or intensified in Europe in the last decade. The European Association of Poisons Centres and Clinical Toxicologists forms the most powerful and Europe-wide expert network.

In 2011, the Public Health Project “Alert System for Health Threats” (ASHT, sponsored by the European Commission and the 7 project partner organizations) had designed and tested a surveillance system that can collect a vast number of exposure cases reported to PC in real time. This system facilitates the timely concomitant analysis of all cases submitted to detect unusual and hidden poisoning risk in a more sensitive way in the near future.

In conclusion, toxicosurveillance of population poisoning risks, enabled by PC’s toxicovigilance, has played an important role in detecting unexpected poisonings, especially poisonings caused by intended use of unsafe products in the past, and will play an even more important role in the future powered by rapidly reacting PC networks.

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THE RELEVANCE OF CLINICAL WORKPLACE LEARNING AND ASSESSMENT IN CP&T
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