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.

Disclosure of Interest: None declared.

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.

Disclosure of Interest: F. Curtin: shareholder of GeNeuro SA; employee of GeNeuro SA.

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, pharmcoepidemiology), 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.

Disclosure of Interest: None declared.

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 been 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.

Disclosure of Interest: None declared.

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

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Summary: Educational reforms over a century ago established a theory to practice undergraduate medical curriculum design, in which "theory" equated with biomedical science. It is remarkable that a theory of professional knowledge that is so old has been so little challenged. We continue to assume that mastery of a rather limited canon of knowledge will lead inductively to practical competence and are surprised and disappointed when it does not. Donald Schön has written about the tension between the "high ground" of the universities and the "swampy lowlands" of practice. Gradually, the swampy lowlands have gained scholarly credibility, and a tension is becoming apparent between the competence that is needed to be an effective practitioner and the competencies that are taught in universities. Yet, there is a common desire that medicine should be a scholarly discipline. This presentation explores how theory and practice can best be integrated in the education of safe and effective practitioners. It draws on theories of training design and observational research into how medical students prepare for transition to residency. It aims to answer the question "how can medical students best prepare to prescribe effectively after starting their careers as doctors"?
Disclosure of Interest: None declared.

GENETICS OF TREATMENT RESPONSE IN DEPRESSION

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Summary: Up to 60% of depressed patients do not respond completely to antidepressants (ADs) and up to 30% do not respond at all. Genetic factors contribute for ~50% of the AD response. During recent years, the possible influence of a set of candidate genes as genetic predictors of AD response efficacy was investigated by us and others. They include the cytochrome P-450 superfamily, the P-glycoprotein (ABCB1), the tryptophan hydroxylase, the catechol-O-methyltransferase, the monoamine oxidase A, the serotonin transporter (5-HTTLPR), the norepinephrine transporter, the dopamine transporter, variants in the 5-hydroxytryptamine receptors (5-HT1A, 5-HT2A, 5-HT3A, 5-HT3B, and 5-HT6), adrenoreceptor β-1 and α-2, the dopamine receptors (D2), the G protein β3 subunit, the corticotropin-releasing hormone receptors (CRHR1 and CRHR2), the glucocorticoid receptors, the c-AMP response-element binding, and the brain-derived neurotrophic factor. Marginal associations were reported for angiotensin I–converting enzyme, circadian locomotor output cycles kaput protein, glutamatergic system, nitric oxide synthase, and interleukin 1-β gene. In conclusion, gene variants seem to influence human behavior, liability to disorders, and treatment response. Nonetheless, gene × environment interactions have been hypothesized to modulate several of these effects.
Disclosure of Interest: None declared.

ETHICS AND PRIVACY OF BIOBANKS

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Summary: The advances in genetics and informatics have stimulated research involving biobanks. Research using samples and data involves privacy risks. Identifiability and its degrees have implications on determining the risk/benefit ratio of a research project. Although the need to protect confidentiality and to put in place security measures is widely recognized, terminological confusion and philosophical differences dominate the ethical and legal discussion about confidentiality of data and samples. Different mechanisms, such as coding or anonymization, influence not only privacy risks of those who supplied the biological samples but also determine whether it will be possible to communicate the results of any genetic analysis back to the research participants. Moreover, it is generally admitted that donors have the right to opt out of a biobank. This means that they may ask for destruction or unlinked anonymization of samples and data. Both can only be carried out if a link is kept between the donors and their samples and data.

In this presentation, different strategies of anonymization and coding will be described and ethical and legal arguments in favor and against them will be discussed, based on the framework of international ethical guidance and human rights implemented in Europe.
Disclosure of Interest: None declared.

ENCEPP: STRENGTHENING METHODOLOGY, TRANSPARENCY AND INDEPENDENCE

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Summary: The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), coordinated by the European Medicines Agency, has seen rapid growth in recent years and now accounts for >170 partner organizations, including research centers, therapeutic networks, and data source owners. The increase in pharmacoepidemiology research via networks such as ENCePP is a clear trend to make best use of available data and expertise, through the conduct of high-quality, independent, and transparent studies focusing on safety and on benefit/risk. Through ENCePP, there is an enhanced capacity to plan and perform postauthorization studies that are essential to the monitoring of safety and efficacy of medicines throughout the product lifecycle.

In addition to increasing capacity for important observational research as requested by regulatory authorities and providing a readily available pool of pharmacoepidemiology expertise, ENCePP has been instrumental in developing tools that translate guiding principles into research practice. The network's outputs include a Code of Conduct, a guide on methodologic research standards, and a Checklist for Study Protocols. These are all cited in the recently published module VIII of Good Vigilance Practice on PASS. A database of studies developed through ENCePP is currently serving as the EU PAS Register, where companies register their PASS in compliance with the provisions on transparency in the new PhV legislation. The EU PAS Register welcomes registration of studies conducted worldwide.

Current opportunities for the network include sourcing of sustainable funding for the partner organizations and existing networks involved, perceived barriers to sharing of data for studies applying for an ENCePP Study Seal, and extension of the network to research centers outside of the EU. Overcoming these challenges is important to the continued success of the network.
Disclosure of Interest: None declared.

MEDIATOR (BENFLUOREX), A FRENCH AND WORLDWIDE PUBLIC HEALTH DISASTER

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Summary: Mediator® (benfluorex), a French and worldwide public health disaster

Irène Frachon, MD

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Benfluorex (brand names Mediator®, Mediaxal® , Lipascor®; drug company Servier) was marketed in France and worldwide until 2009. This marketing authorization was held while the compounds