





European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices/Pharmaceutical Care (CD-P-PH/PC)

Nurses' Perspectives

Council of Europe Resolution on good reconstitution practices – A major contribution to the safety of patients receiving reconstituted medicines

CM/Res (2016)2

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European Federation of Nurses Associations
Nurses' Voice

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European Federation of Nurses Associations (Established in 1971)

36 Member Countries

Represents **3 million** nurses/midwives in the EU

- **Independent** voice of the nursing profession
- **Mission** is to strengthen the status and practice of the profession of nursing for the benefit of the health of the citizens of Europe and nursing

Patient Safety Priorities:

- ✓ Impact of COVID-19 - **retention** and **recruitment**
- ✓ Working **conditions** and safe environments
- ✓ Healthcare **expenditure** and **efficiency**
- ✓ Shift from inpatient care to **primary care**
- ✓ **Long-term care** and to the **ageing** population



<http://www.efn.be/>



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Policy Drivers (Patient Safety and Quality)



Political

- Universal Health Coverage
- Covid-19 impact
- Economic implications – efficient and effective use of resources
- Epidemiological patterns – NCDs, chronic diseases, ageing population
- Shortage of health professionals
- Rural vs urban populations
- Technology enabling changing models of practice

Societal

- Quality and safety of healthcare – outcomes of care
- Timely and cost effective health care
- Changing disease and disability patterns

Professional

- Scopes of practice are rarely exclusive but closely bound with issues of regulation or licensing
- Duplication and gaps in service
- Ethical principles essential to quality of care and safety
- Increasing specialisation
- Interprofessional education



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Importance of the Resolution



Patient harm due to adverse events:

- 1 in 10 patients are harmed while receiving hospital care globally, 134 million adverse events, 2.6 million deaths annually in low and middle income countries (WHO Global Action on Patient Safety 2019, Jeddah Declaration on Patient Safety 2019)
- Unsafe medication practices and medication errors are a leading cause of injury and avoidable harm in health care systems across the world (Global cost is estimated at \$42 billion USD annually). Errors can occur at different stages of the medication use process
- Medication errors including those involving inappropriate reconstitution, have serious implications for patient safety

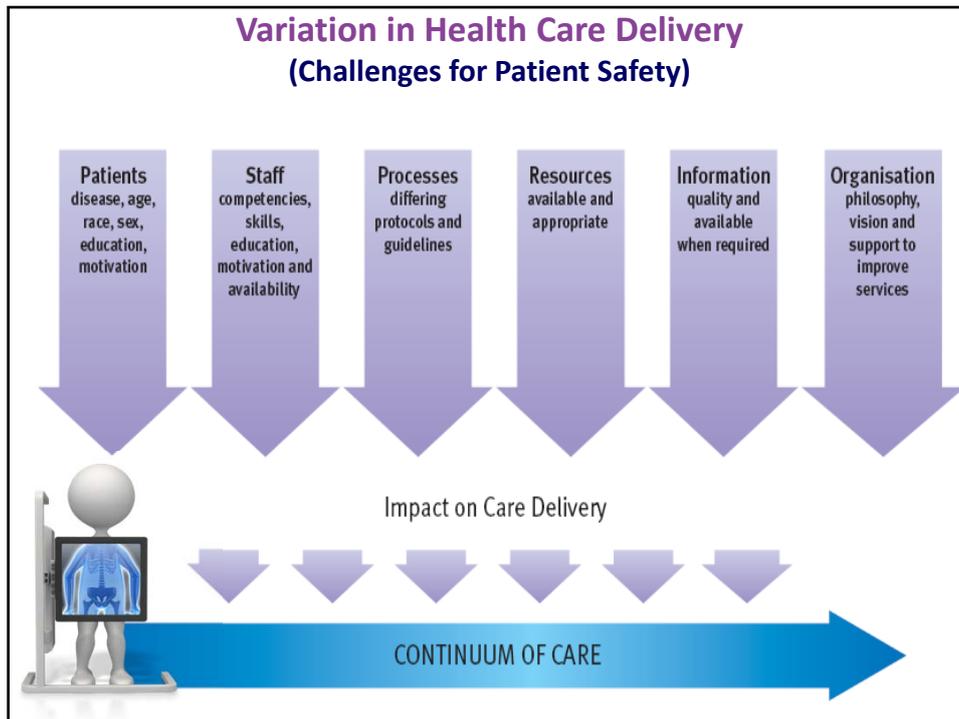
Transposition of the Resolution

by national authorities is critical



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Risk Management

- Nurses are the largest group of health professionals in the majority of countries - harnessing their full capacity offers the best possibility for transforming health-care system
- Nurses and midwives play a pivotal in **clinical risk management** and promoting patient safety in health care domains on a daily basis (e.g. patient assessments, activities of daily living, wound management, falls etc)
- Nurses and midwives can be a knowledgeable asset to informing the Risk Management Principles:
 - Risk identification
 - Risk assessment
 - Risk management
 - Risk acceptance
 - Risk review



Evolving Scopes of Practise



Nurses can legally prescribe for example in:

- Cyprus, Estonia, Finland, Netherlands, Poland and Spain adopted laws in the past decade
- Australia, Canada, Ireland, New Zealand, Norway, South Africa, Sweden, United Kingdom, United States of America etc have expanded authority in place over 10yrs

Significant difference in legal and regulatory framework:

- Variety in the application to the whole profession – grades
- Different models of prescribing
- Diverse care settings
- Variance in scope of practice (e.g controlled drugs etc)



United Kingdom – extended to non medical prescribers (50,000 plus)

Gielan et al, (2014). *The effects of nurse prescribing: A systematic review*. International Journal of Nursing Studies, No 51, pp 1048 - 1061

Interprofessional Improvement Initiatives

Six Determinants:

- Site receptivity – management/ active partner / good governance
- Leadership – champion (designated person)
- Team issues – appropriate qualifications and competence (continuous education, maintaining competence, regular training)
- Impact on healthcare relations
- Impact on quality and safety issues
- Institutionally embedded - legitimisation

(Greenfield D, Nugus P, Travaglia, J, et al. BMJ)

- **Integrative philosophy:** commitment towards **collaboration**, values all contributions (respect, conflict resolution, role clarity, working relationships, collaborative culture)
- **Collaborative work** is challenging and complex, but it is work worth doing



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Directive 2013/55/EU in a nutshell



Recognition of Professional Qualifications aims to facilitate the free movement of EU citizens by making it easier for professionals qualified in one member state to practise their profession in another

- Key elements: sectoral professions, European Professional Card, Alert mechanism, common training principles (minimum requirements, common frameworks, competencies), language requirements, partial access, mutual evaluation (compensatory measures: adaptation period aptitude test)
- **CPD:** Article 22 (b) Member States required to encourage CPD and support updating of knowledge, skills and competences in order to maintain a safe and effective practice and keep abreast of professional developments

Transposition by national authorities



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Benefits of the Resolution

Patient benefits:

- Improves patient safety and quality of care
- Risk assessment approach that reduces potential harm

Increasing effectiveness - benefits:

- Prevents cost of adverse harm
- Robust standard approach to reconstitution of medicines and opportunities for ongoing quality improvement
- Provides clear governance and collective responsibility (buy in from the whole organisation)
- Reduces duplication of effort
- Supports behavioural change- leads to – and enables innovative and creative approaches

Team benefits:

- Provides the framework for interprofessional collaboration and partnership
- Improves transparency, trust, supports inclusive relationships
- Increases the competence and knowledge of the whole team and multidisciplinary prescribing decisions.



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Final Thought

Working in collaboration supported by appropriate **policy, legislation, education, leadership, management, resources** and **research**, the Council of Europe Resolution on good reconstitution practices – is an important tool to contributing to the safety of patients receiving reconstituted medicines (CM/Res (2016)2) and will:

- be responsive to patient needs and service demands
- strengthen influence on policy, design, delivery and evaluation of services
- increase the impact on improving the health and well being of patients

Thank You



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