

# **Future regulatory challenges in eHealth**

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# Making sure patients and the public obtain medicines and other pharmacy services safely online



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# Context



- Growing number of online primary care services using new technologies
- Complex and constantly changing service models
- Both benefits and risks to patients
- Legislation and regulation not designed for these new models and gaps exist in regulatory landscape

# Strengthening safeguards for patients

- Different organisations and agencies are responsible for different elements of online healthcare services
- We are working closely with other regulators involved
- We want to strengthen our guidance for pharmacy owners who supply medicines and other pharmacy services online
- [https://www.pharmacyregulation.org/sites/default/files/document/discussion\\_paper\\_on\\_safe\\_online\\_pharmacy\\_june\\_2018\\_0.pdf](https://www.pharmacyregulation.org/sites/default/files/document/discussion_paper_on_safe_online_pharmacy_june_2018_0.pdf)

# 1. Transparency and patient choice

- Patients must have enough information about the service and who is providing it to make an informed choice and to be able to raise concerns
- Pharmacy owners have an important role to play in supporting and raising awareness with patients about what they should expect from a safe and effective pharmacy service

## 2. How to ensure medicines are clinically appropriate for patients

- How websites offering medicines for sale or prescription are set out e.g. can patients select a prescription only medicine and it's quantity before consulting prescriber
- What processes pharmacy owners have in place for the pharmacy team to make appropriate checks and to identify possible risks to patients

### 3. Further safeguards for certain categories of prescription-only medicines

Such as:

- Antimicrobials (antibiotics)
- Opiates/ sedatives
- Medicines or medical products for chronic conditions (including asthma and diabetes) and mental health conditions
- Non-surgical cosmetic medicinal products (such as Botox)

## 4. Regulatory oversight



If a pharmacy owner decides to work with prescribers or prescribing services operating lawfully outside the UK, they must make sure:

- they successfully manage the additional risks that this may create;
- the prescriber is registered in the country where the prescription is issued and working within that country's legislation, and
- that they are complying with national prescribing guidelines for the UK.





# Future regulatory challenges in eHealth A Physiotherapy Perspective

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**Chair, European Region-WCPT**

HPCB Mobile professionals, safe patients Conference Dublin 4<sup>th</sup> Feb 2019



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# World Professional Org- WCPT



109 Member organisations; 450,000 physiotherapists  
Africa, Asia Western Pacific, EUROPEAN,  
North America Caribbean and South America



# European Region 1998-

- *The voice of physiotherapy to the European and EU authorities*
- An organisation of professional organisations from 38 (40) countries that must be members of WCPT; represents approx. 180,000 PTs
- Non-profit, non-governmental, independent org. funded by Member Organisations (MOs) subscription fees
- Office and secretariat in Brussels





# European Region



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*To investigate and disseminate good practices in  
the use of  
eHealth to Improve Patient Care and  
Physiotherapy Services ”*

## Briefing Paper

ADOPTED

General Meeting 26 – 28 April 2018

Dublin, Ireland



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# eHealth in Physiotherapy

Briefing paper:

- 1. Extent / potential** of eHealth in physiotherapy
- 2. Challenges /Barriers in the use of eHealth in physiotherapy practice**
- 3. Laws & Regulations** – national & regional
- 4. Future and Recommendations**



# Domains within eHealth in Physiotherapy

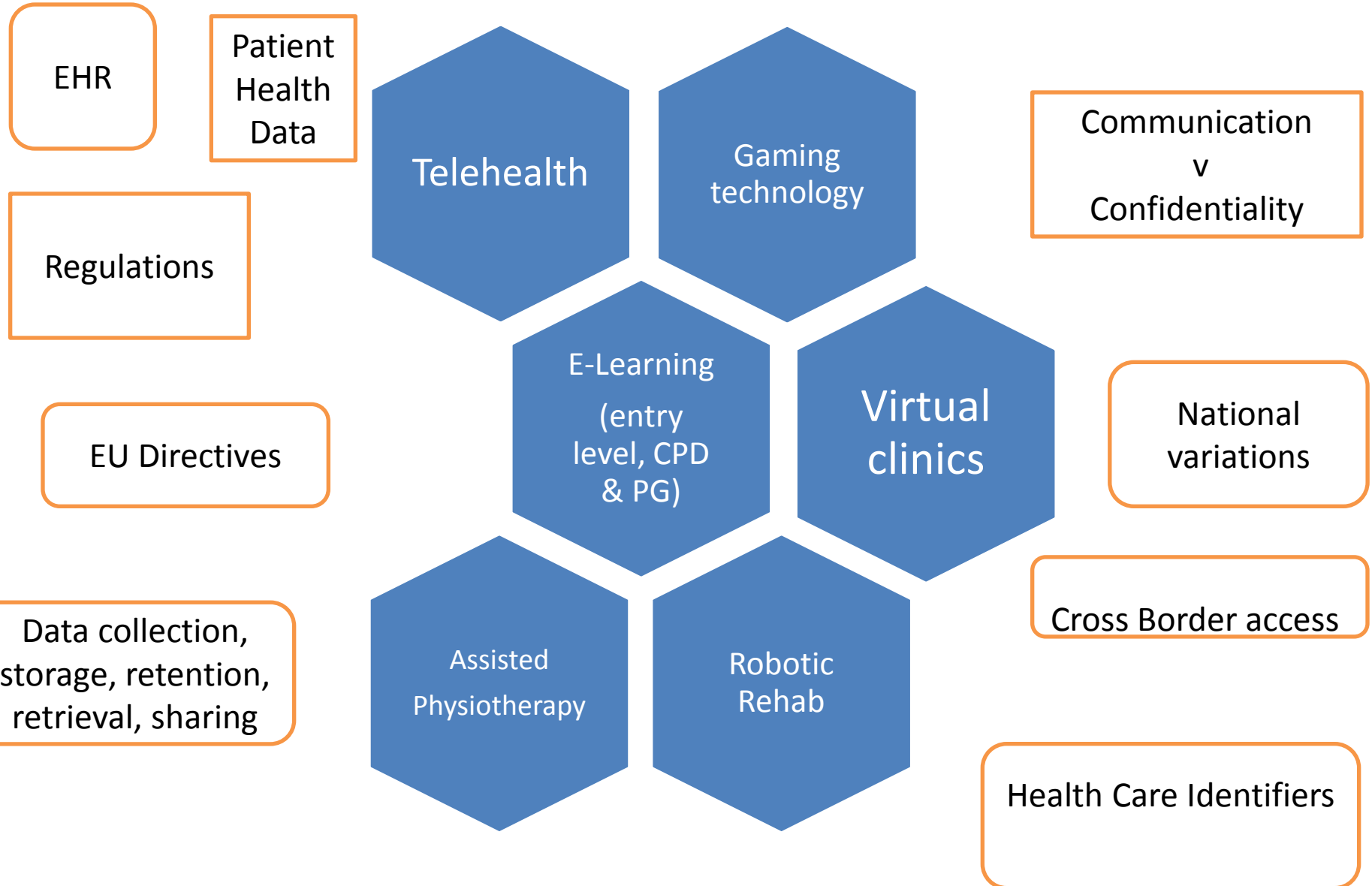
1. Management and Administration  
logistics and supply  
of health related  
goods and services

2. Clinical  
evaluation and  
research  
collaboration

3. eLearning and  
eSkills

4. Wellness and  
disease  
management

# Opportunities and Challenges





# eHealth in PHYSIOTHERAPY



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Opportunity	Examples
Delivering services in remote areas	telemedicine sessions
Supporting teaching	webinars, online courses
Shortening of waiting times	virtual fracture clinic, ...
Easier monitoring of training and patients state	FitBit, iWatch, ...
Managing patients motivation	virtual reality training tools
Directing patients PT-related actions	eExercise
Lowering costs	telehealth
Better solutions for prevention of different health states	blogs, social media campaigns, PT-led (or PT included) new developments

***Working with eHealth should result in a more efficient (qualitative) use of available time***



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# Challenges – Terminology



## OPPORTUNITY

*The use of these eHealth tools and services enhance content, quality and clarity, together with readability and therefore allowing the quality of care to be more efficient and effective.*

## CHALLENGE

- ❖ **The lack of common and specific physiotherapy terms in programmes/services in the use of e-tools**

## RECCOMENDATION

*Interoperability and the use of exact terms and references are the keystones in order for a system like this to work.*

# Challenges - Legal and Regulatory

- Legal aspects at a national and international level

Issues concerning healthcare data (good practices, privacy, regulation & standardisation of eTools) are, in most countries, not yet fully incorporated in national laws and regulations

- EHRs

Some EU MS do not have specific national laws about informing patients on EHRs, the duty to inform the patient is then based on the general European and national **data protection legislation**.

- Cross-border access to EHRs

A Regional legal framework for the use of EHRs (including cross-border health care) does not exist

(Only 8 countries incorporated a legal framework for cross-border health data access into their legislation)

- Common Interoperable Platform

Due to the vast differences between the MS a common interoperable platform is not yet possible.

Therefore cross-border healthcare data regulations will in the future follow national implementation procedures and timeframes.



## Challenges –Mind set

- **Paradigm shift in thinking** both for the patient and the physiotherapist regarding privacy (health data collection, storage and sharing) and other eHealth services.
- Promotion and advocacy is required in the form of information through media and social media.

# Challenges – Relationship

- PT has evolved - a mix of high tech Assess & Trx in combination with manual interventions.
- Using eTools and eServices should be to the advantage of both the patient and the physiotherapist in regards to effectiveness and safety but it can mean a change in the therapeutic relationship.

# Challenges –Management



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Physiotherapist Managers need to organise working conditions in a way that supports innovative solutions.

Change Management

Leadership

Re-organisation

(positive impact on addressing the time barrier).



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# Challenges – Competencies

## Having eHealth competencies

- The ability to work in an increasingly electronically mediated health-care environment and to use technologies ranging from email and electronic records, to informatics or big data.

### Groupings of competencies to consider:<sup>1</sup>

1. Basic Computer Skills
2. Clinical Information Management Competencies
3. Informatics Literacy

<sup>1</sup>[www.physiotherapyalberta.ca/](http://www.physiotherapyalberta.ca/)

competent = the knowledge, skills, and attitudes required to perform a certain skill or engage in a specified activity

# Challenges - Standards



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National PT orgs (professional orgs & quality institutes) must take a consulting role in setting out standards for eTools and eServices taking into account -

- ❖ patient safety,
- ❖ standardised use of language and terms,
  - ❖ relevance to scope of practice and
  - ❖ continuous possibility of use.





# Challenges –???

## Cost and time implications

- Purchasing a device or service,
- learning how to properly use it
- continue to effectively using it,
  
- Initial costs are high

# Challenges - eHealth Strategies



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1. National eHealth regulatory strategies lack the inclusion of the physiotherapy practices within their legal structures.

## Recommendation (ER-WCPT)

1. eHealth strategy implementation has to be supported by interoperable eHealth systems that should be regulated.

2. eHealth national and European strategies have to include the physiotherapeutic aspect of care.

- [www.ehealthireland.ie/Knowledge-Information-Plan/eHealth-Strategy-for-Ireland.pdf](http://www.ehealthireland.ie/Knowledge-Information-Plan/eHealth-Strategy-for-Ireland.pdf)

- eHealth Ireland Committee

# Addressing the Challenges



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- ✓ ***“Make eHealth tools more effective, user-friendly and widely accepted”*** – (EU Commission) has to include in it the eHealth practices of the physiotherapy profession and so regulation and standardisation measures should be extended beyond the medical and nursing professions.
  
- ✓ Further actions should be taken at EU level to be able to monitor development of the physiotherapy practice pertinent to eHealth measures (that are mostly focusing on enhancing the quality of physiotherapy services).
  
- ✓ Share the knowledge and practices as effectively as possible (ER-WCPT can support) e.g. Insight Centre for Data Analytics  
[https://doi.org/10.5072/FK2.ucdlib\\_33020](https://doi.org/10.5072/FK2.ucdlib_33020)
  
- ✓ ER-WCPT advocates that its Member Organisations embrace eHealth-
  - incorporate into UG curriculum,
  - monitor changes and developments in PT education
  - include CPD-courses on e-health and
  - develop ehealth CPD.