

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



10 YEARS OF
CO-OPERATION



Health Professionals in the Blood sector *State of Play – Result from a focus group survey*

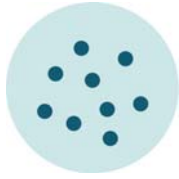
*Keeping up with Reality and Quality: A challenge for
European Blood Establishments*

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EDQM/Council of Europe

On behalf of the B-QM WG

WHAT WE OBSERVED ?



Observations (B-QM audits, BEs feedback, B-QM WG)

- Difficulties in **hiring** certain categories of **personnel/health professionals** with the required qualification to perform duties laid down in the blood legislation,
- **'demographic changes'** among health professionals,
 - e.g.
 - *Eastern countries report a "brain drain" from the East to West as a consequence of the free movement of healthcare professionals*
 - *Decline in the number of qualified physicians holding a specialisation in blood transfusion*
- Thus the need for **CHANGE IN SCOPE OF PRACTICE**
 - **Redeploy duties to other categories** of health professionals *e.g. Donor medical assesement from physicians to nurses* , to ensure blood supply continuity
- However: **permissive** versus **protective/restrictive** regulation

HEALTH PROFESSIONALS

Regulated at **national** level and **EU** level:

- **National legislation:** educational requirements, the use of the professional title, the skills and fitness to practice
 - Trade unions/professional bodies may also have laid down protective measures for given professions.
- **EU legislation - Directive 2005/36/EC** - sets up a system for the **recognition** of professional qualifications in the European Union (EU) and foresees automatic recognition for physician, nurses, dentists, pharmacists and mid-wives.
- **EU Blood legislation** – requires qualified personnel but doesn't require categories of health professional for duties.



Note: differences in qualification/ qualification level requirements for other categories of health professional exist between countries, impeding their recognition.

A FEW DEFINITIONS

- **QUALIFICATION – Attested degree or professional experience ► Evidence**

2005/36/EC: 'professional qualifications': qualifications attested by evidence of formal qualifications, an attestation of competence referred to in Article 11, point (a) (i) and/or professional experience;

'evidence of formal qualifications': diplomas, certificates and other evidence issued by an authority in a MS [...] certifying successful completion of professional training obtained mainly in the Community.

- **SCOPE OF PRACTICE -** Describes the **services** that a qualified health professional **is deemed competent to perform**, and permitted to undertake – in keeping with the terms of their professional license - nursingworld.org

- **FITNESS TO PRACTICE -** Refers to any **attribute, which proves that a health professional has the skills, knowledge, character and health** to practice safely and effectively. <https://www.hcpc-uk.org/concerns/what-we-investigate/fitness-to-practise/>



Approaches used vary from one country to another. It is often demonstrated via a license, or being registered in a database

CHANGE IN SCOPE OF PRACTICE

Advanced research and developments on the topic: AUSTRALIA, US, CANADA



Altman, Stuart H., Adrienne Stith Butler, Lauren Shern, Advancing Health Committee for Assessing Progress on Implementing the Recommendations of the Institute of Medicine Report The Future of Nursing: Leading Change, Institute of Medicine, et Engineering National Academies of Sciences. *Removing Barriers to Practice and Care*. National Academies Press (US), 2016.

NCSBN. « Changes in Healthcare Professions' Scope of Practice: Legislative Considerations », 2006. <https://www.ncsbn.org/4625.htm>.

<https://cpsns.ns.ca/wp-content/uploads/2017/10/Change-in-Clinical-Scope-of-Practice-Frequently-Asked-Questions.pdf>

<https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Ensuring-Competence>

CHANGE IN SCOPE OF PRACTICE Cont'

Scope of practice is defined by:

- Patients the professional cares for,
- The procedures performed,
- Treatment/care provided,
- Practice environment,
- Education, training, certification,

Usually, is **not a change in scope of practice:**

- Patient demographic changes,
- Emergence of a disease,
- Development of treatment/diagnostic modalities.

Change in scope of practice:

- **Significant** change to any of the factors set out in the description of scope of practice, *e.g. when a carer wishes to return to a scope of practice in which he/she has not practiced for several years*
e.g. nurses taking over medical duties in rural environment

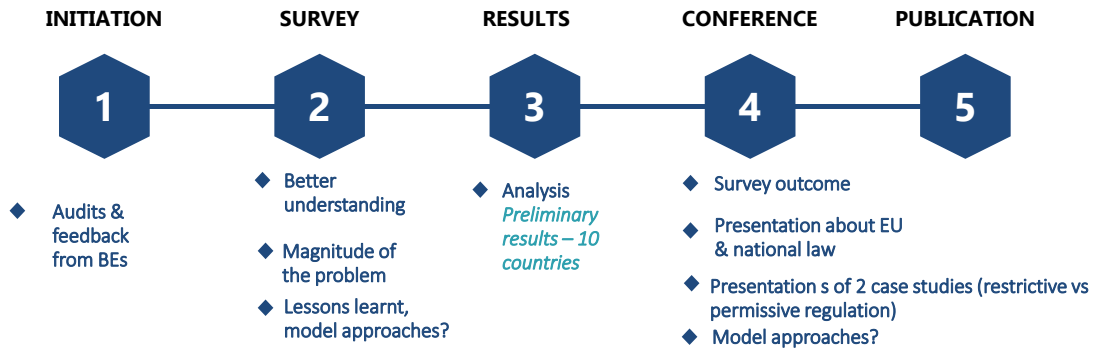
► Required to inform competent Member State organisation (e.g. college of nurses)

WEAK OR STRONG SIGNAL?



METHODOLOGY & SURVEY

- **Desk-based** research,
- **Focus group survey** – B-QM working group (12 countries)
 - ▶ Survey protocol
 - ▶ Structure survey - 3 parts:
 - General information on health professionals working in BEs and current state of play,
 - Change of scope of practices,
 - Risks, benefit, lessons learnt from change of scope of practices.



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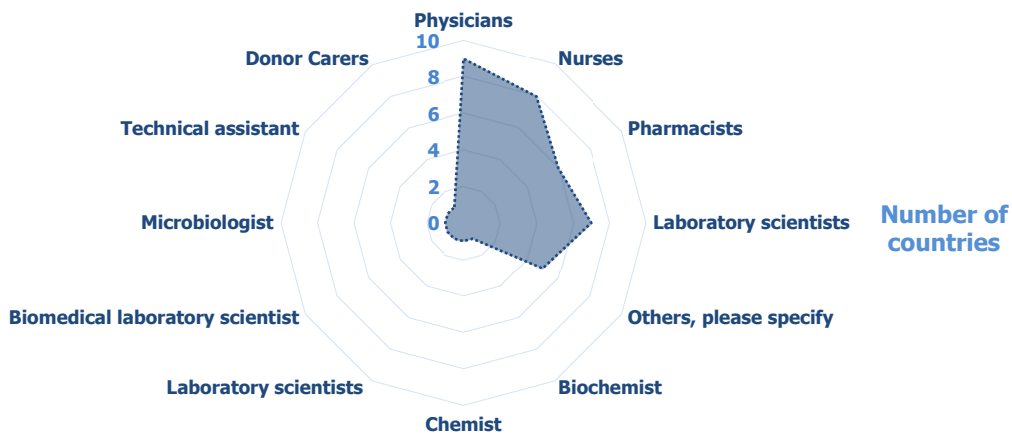


WHAT DO WE LEARN FROM THE SURVEY?

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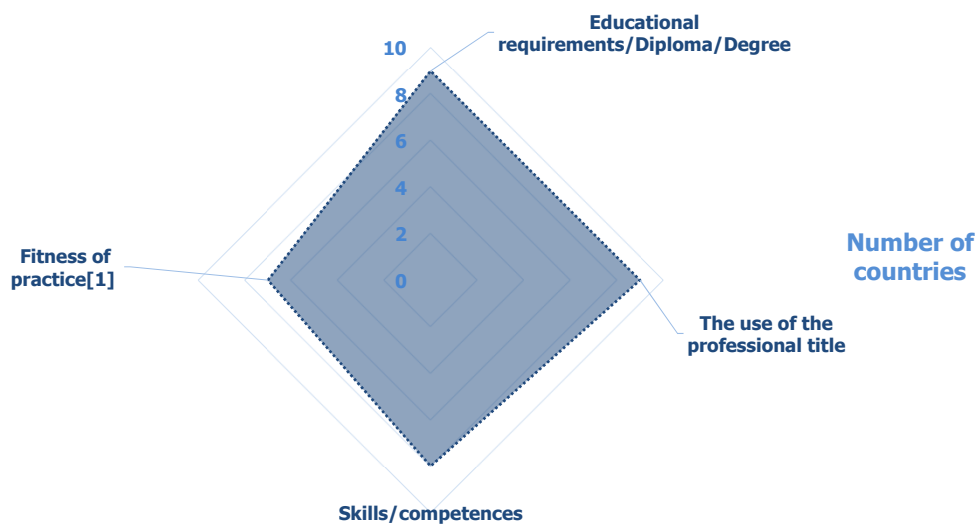
HEALTH PROFESSIONALS REGULATED AT NATIONAL LEVEL



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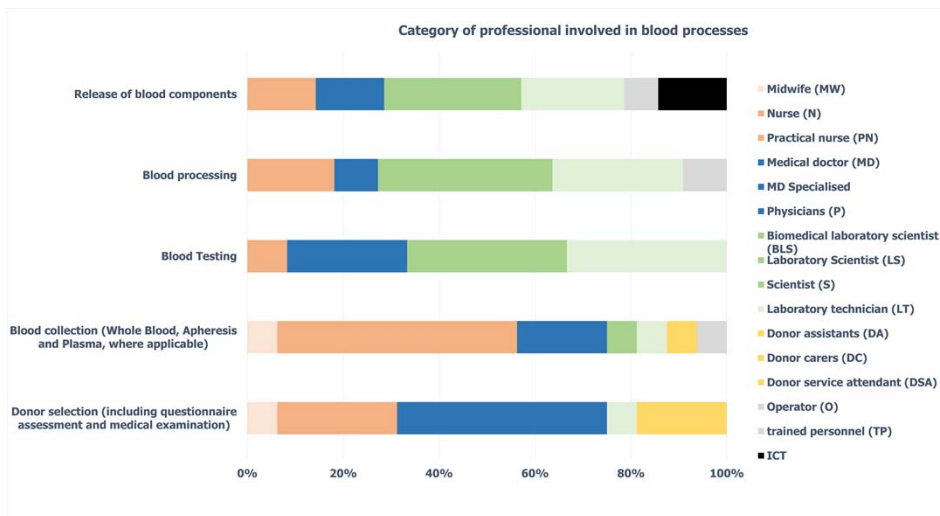
WHAT DOES THE NATIONAL LEGISLATION REGULATE ?



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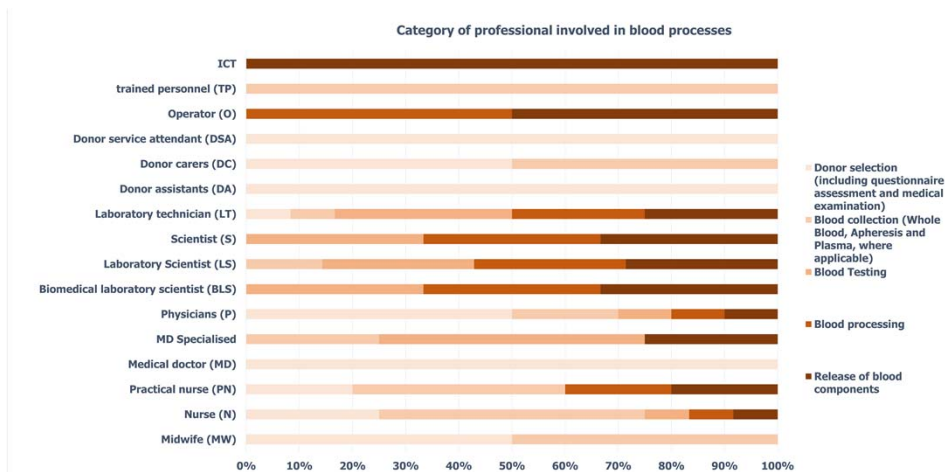
CATEGORY OF PROFESSIONALS IN THE BLOOD SECTOR



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CATEGORY OF PROFESSIONALS ALONG THE BLOOD SUPPLY

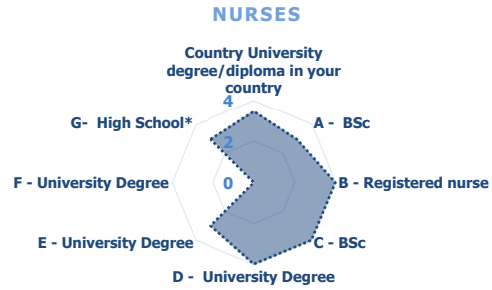
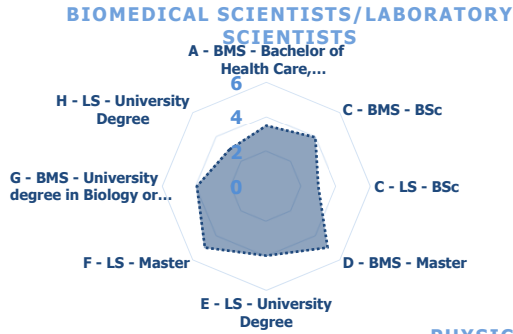


► 4 out of 10 countries: health professionals working in BEs differently regulated, e.g. stricter national legislation, specific requirement in the national blood legislation

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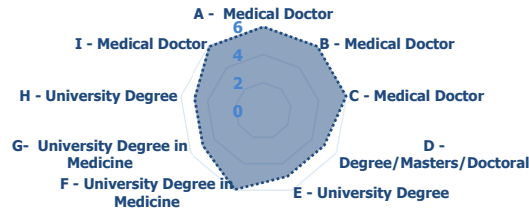


NUMBER YEARS OF UNIVERSITY ('COUNTRY'- 'DEGREE')



Number of Years

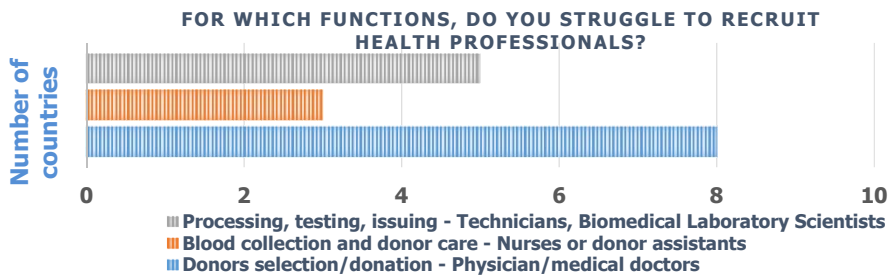
PHYSICIANS/MEDICAL DOCTORS



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ISSUES & OBSTACLES (1)



Physicians/MD: *Too specific/narrow medical role, *no sufficient doctors/few applications*few have specialisation, *not interested as most of them are working as family doctors, with high income (not attractive, lower salary, unknown field), *Restrictions for employment- for each post - need approval from the Ministry of Health.

Nurses/donors assist: *not sufficient applicants *Competition with other health providers, * would prefer professionals with a higher educational level esp. in the COVID-period.

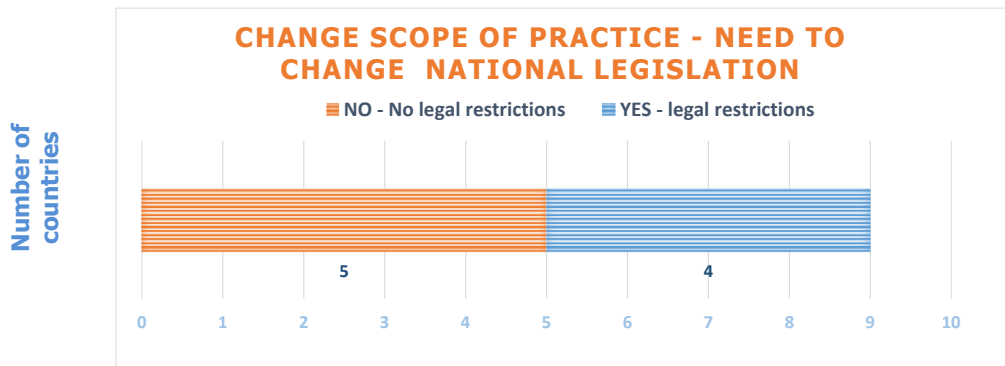
Lab tech. BLS: *not sufficient applicants,*Competition with other health services,* Restrictions from MoH.



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ISSUES & OBSTACLES (2)



1 country: Resistance by Union, unless there is a specialised register for nurses, union will not agree.

CHANGES OF SCOPE OF PRACTICE

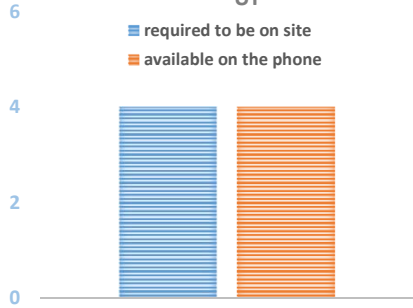
5 out of 10 countries have implemented, will implement or have examined the possibility



Country A	Done	Physicians ► Nurses: Nurses are trained to be consultants in donor selection process Biomedical laboratory scientists are taking care of the night shifts in Blood Group Laboratory instead of Candidates of Medicine (students)
Country D	Done To be done	Scientists ► Operators: Implemented changes last year in production to move certain activities from scientists to operators. Now reviewing Medical Laboratory Scientist activities.
Country E	To be done	Physicians ► Nurses: Donor pre-donation assessment/screening to be performed by nurses with an MD being available all the time. Laboratory aids: Introduce laboratory aides for specific tasks, <i>e.g. processing of blood, always under the supervision of a lab scientist</i>
Country I	Examined	We have examined the possibilities but because of several reason: no possibilities to supervise real-time digitally, not enough donor assistants, who have the educational level of a nurse, we don't think we can implement such a change in the near future.
Country H	Done	Physicians ► nurses/donor care in donor selection and collection Blood Collection, including venepuncture performed by Donor Carers. Lab scientists: Fewer registered laboratory scientists employed in testing and processing. Increase in number of non-qualified laboratory technicians

CHANGE SCOPE OF PRACTICES - DONOR INTERVIEWS FROM PHYSICIANS TO NURSES/OTHERS

PHYSICIANS –EXTENT OF BACK-UP



Extent a nurse/another health professional can decide on medical issues and adverse reactions during collection:

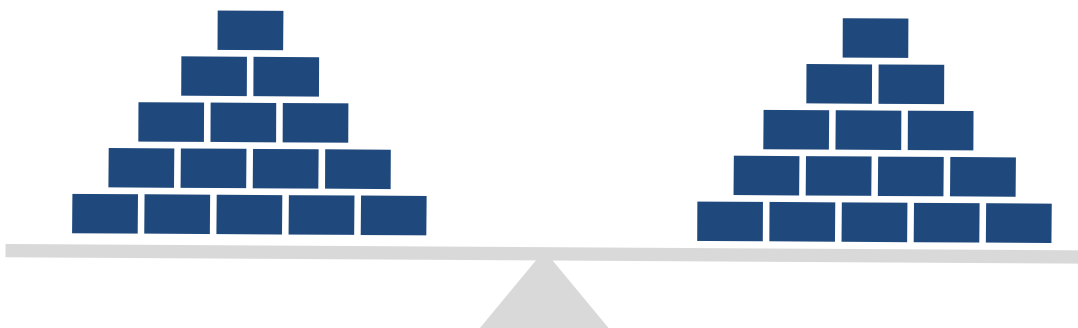
- Trained professionals,
- SOPs are in place,
 - 1 case: only SAR require consulting physicians
 - 1 case: MD to be informed and to decide on the treatment based on donor clinical evaluation
 - 2 cases: trained professionals and SOPs when to consult the physician

SOME CONSIDERATIONS.....

-
- How about ensuring health professionals are protected and sustained (e.g. MD, BMS) while there is a decreased interest in those professions in the blood sector?
 - What about relying uniquely on decision making algorithms (Artificial intelligence) for the release of blood components?
 - How about valuing and protecting health professionals, which take over additional duties/widen their scope of practices (*e.g. nurses*)?
 - How about ensuring the continuity of blood supply in countries where the legislation is not permissive to change in the scope of practice?
 - How to mitigate risks in changing the scope of practices?

KEY QUESTION

**Can we find the right balance,
that takes into account all stakeholders (Legislators, Unions, BEs, Health Professionals)
views to
ensure continuity of blood supply?**



ACKNOWLEDGMENTS

B-QM WG Group Members & former Members EDQM

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Jan Ceulemans, Belgium
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POLLS

- 1. All the audience: After this presentation, do you have a better understanding of what is 'change in scope of practice' – YES/NO**
- 2. BEs: Do you experience difficulties to recruit certain category of health professionals in your Blood Establishment? YES/NO**
- 3. BEs: In the near future, do see the need to have change in the scope of practice for certain health professionals in your BE? YES/NO**
- 4. What 'changes in scope of practice' would there be? Transferring duties from:**
 - physicians to nurses**
 - physicians to donor assistants or other professionals**
 - biomedical scientists to technicians/operators**