International Federation on Ageing

Eye See You

Perspectives on Emerging Biosimilars in Ophthalmology in Canada

Summary Report of Expert Stakeholder Interviews

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For queries relating to this document,
please contact: astancu@ifa.ngo

Background

A National Consultation on the Use and Implementation of Biosimilars was undertaken in 2019 by the Canadian Agency for Drugs and Technologies in Health (CADTH) to support the uptake of biosimilars across Canada. Ophthalmology was identified as a therapeutic area of consultation, for which stakeholder perspectives on biosimilar policy options were solicited.[1] The CADTH consultation provided baseline information on stakeholder awareness on the appropriate use and implementation of biosimilars and identified critical knowledge gaps among older adults and their caregivers, patient and advocacy organizations and professional associations across therapeutic areas including ophthalmology.

As biosimilars in ophthalmology are not currently available in Canadian therapeutics, and biosimilar policies are recently emerging in some provinces, the International Federation on Ageing conducted in-depth stakeholder interviews to ascertain how to best respond to the knowledge gaps within the rapidly evolving ophthalmology field and inform emerging biosimilar policies. Stakeholders identified considerable concerns over the current landscape of biosimilars in ophthalmology centred around three core issues: person-centredness, access and safety.

Person-centredness

Progressive vision loss such as age-related macular degeneration (AMD) and diabetic retinopathy (DR) can be managed through regular and ongoing ophthalmic interventions from a team of vision health care providers.[2] The effectiveness of AMD and DR interventions is often dependent upon adherence to treatment regimens and may be influenced by the degree of trust and support shared by an individual with their team of vision health care providers. Stakeholders suggest there is insufficient guidance to overcome knowledge gaps about the appropriate use of biosimilars in ophthalmology and to build the necessary trust among older Canadians, their caregivers and vision health care providers around expected vision health outcomes.

In addition, AMD and DR may often accompany other chronic medical conditions, which may give rise to apprehension around polypharmacy and medication management. This apprehension is often amplified among older people who are likely to experience higher rates of depression and anxiety, as well as challenges with mobility according to the World Health Organization (WHO) World Report on Vision.[2] As such, changes to medications and care pathways may have a profound impact on treatment adherence and subsequent health outcomes.

Aligned with the WHO Integrated Care for Older People (ICOPE) guidelines, stakeholders agree that any health care policies, including those pertaining to the use of biosimilars in ophthalmology across Canada, must be founded upon the needs of the individual to effectively prevent the decline of intrinsic capacity and/or maximize functional ability.[3] An essential consideration herein is to ensure the treatment pathway is responsive to the needs and concerns of older Canadians seeking ophthalmic interventions. Further to the WHO World Report on Vision, stakeholders call for a consideration of integrated people-centred eye care (IPEC) which would provide a continuum of vision care according to their needs throughout the life course.[2]

To date the engagement of older Canadians with vision loss, their caregivers and health care providers has been insufficient in defining an appropriate biosimilar policy framework which would reconcile and align with good practice including the WHO ICOPE guidelines.

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The inadequate level of awareness of biosimilars in ophthalmology leads to significant barriers to multiple tenets of an effective public health framework, namely:

- Shared decision-making and goal setting;
- Implementing the care plan using principles of self-management support;
- Ensuring a strong referral pathway and monitoring of the care plan; and
- Engaging communities and supporting caregivers

Access

The 2006 United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) provides a human rights approach to ensuring people with vision loss are able to participate in society on an equal basis with others.[4] Essential to this approach is the equal access to information on and services for vision care regardless of geographic, socioeconomic, and financial factors or health literacy. Interview respondents identified factors that must be considered in the implementation of equitable biosimilar policies to support all older Canadians with vision loss in accessing the most appropriate treatment for their vision health.

A recent report from the Conference Board of Canada reinforces stakeholder concerns that access to ophthalmologists and vision health experts is limited in remote and rural parts of Canada, particularly across Indigenous communities.[5] According to the report, fragmentation of the vision health care delivery framework across Canada has a:

> "Direct impact on standards of care and equitable access to treatment options by Canadians."

Biosimilars in ophthalmology represent a significant opportunity to increase the treatment options for individuals experiencing vision loss through the availability of novel medicines. However, aligned with one of the central tenets of the UNCRPD is the right for individuals to access appropriate medicines and make choices regarding their care.[4] Biosimilar policies which mandate switching of treatment may undermine the right of individuals to access un-funded medications by introducing a significant cost barrier to continuing on an un-funded originator biologic treatment.

Furthermore, mandated switching policies may impact the patient support services available along an individual's treatment differently due to the current disharmony of biosimilar policies enacted and emerging across Canadian provinces and territories. More specifically, differences between rural and urban centres or within long-term care residences may also require changing providers of ongoing vision care services who monitor vision health outcomes and manage medication dosage. Such changes would unnecessarily complicate an already complex health care pathway, introducing potential barriers to accessing new treatments.

Moreover, the WHO World Report on Vision emphasizes the importance of patient education and health literacy in adherence to vision care treatments, ultimately impacting health outcomes.[2] There is a growing risk that a barrier to the appropriate use of biosimilar medicines is the current scarcity of educational resources available about biosimilars in ophthalmology in plain language and in accessible multimedia formats.

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Safety

The long-term impact and effectiveness of therapeutic interventions for eye diseases must be robustly monitored throughout vision treatment course. However, given that vision care is not typically integrated in national health strategic plans, health system infrastructure may be inadequate to ensure post-market surveillance and monitoring of vision treatment outcomes.[4]

To date, stakeholders are unaware of neither studies of the long-term impact of ophthalmology biosimilars compared with their biologic counterparts, nor of adequate surveillance and monitoring mechanisms to track medication adverse reactions or polypharmacy interactions. Aligned with the Conference Board of Canada, stakeholders identified a significant need to prioritize clinical research into the appropriate uses of ophthalmology biosimilars and invest in improving collaboration of primary care providers around vision health care needs.[5]

Furthermore, the paucity in published literature about biosimilars in ophthalmology raises concerns around the basis of emerging biosimilar policies. Stakeholders echoed that a barrier to effective and appropriate use of ophthalmology biosimilars is the insufficiency of research in the Canadian context complementing existing international evidence for biosimilar interventions. Biosimilar policies affecting potentially millions of older Canadians with current and future vision loss must be fundamentally based upon, rather than guided by evidence.

Opportunities for Action

As members of civil society, stakeholders interviewed represent significant patient and advocacy perspectives, and a powerful combined force able to support and inform the appropriate use of biosimilars in ophthalmology. To that end, several opportunities for action were proposed:

1. Older Canadians with vision loss must be empowered to take an active role in managing their health alongside a trusted and supportive vision health team.

   According to the WHO ICOPE framework, shared decision-making begins with a comprehensive assessment of the needs and preferences of individuals with blinding eye diseases and their caregivers.[3]

   A more fulsome understanding of the impact of blinding eye diseases on daily function can inform the development of a standard of care and treatment pathway for biosimilars in ophthalmology. Furthermore, given the long-term treatment needed for AMD and DR, individuals and their caregivers must trust they have the ongoing support of their vision health team, without significant changes to their treatment pathway (i.e. who provides the ophthalmic interventions and at what location.)

   Input and engagement of vision health care providers, older Canadians and caregivers is foundational to developing a person-centred biosimilar policy framework. These stakeholders must have opportunities to contribute lived experiences and professional guidance in public consultations and position papers.

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2. Across Canada there must be equitable access to the best quality, most appropriate and safe and effective treatments to slow or prevent blinding eye diseases.

   Clinical research on ophthalmology biosimilar treatments can meaningfully inform the development of vision health benchmarks and best practices which can respond to the diverse needs of older Canadians with vision loss for the long term. Canadian-specific data on the interactions between biosimilars and other medicines, and long-term monitoring of outcomes must be collected for the effective implementation of biosimilar policies. Supplementing clinical research, educational resources in accessible formats are urgently needed to ensure older Canadians with vision loss and their caregivers have a complete understanding of the appropriate use of biosimilars in managing vision health.

   Moreover, international and Canadian experiences have demonstrated the value of exemptions within biosimilar policies. These exemptions provide individuals continued access to an effective treatment should switching from a biologic to a biosimilar be contraindicated by their health care provider. Access to the most effective and appropriate treatment as determined in consultation with a vision health care provider must be assured for Canadians across all provinces and territories in alignment with the UNCRPD.

3. Biosimilar policies must be responsive to the diverse and evolving needs of individuals across therapeutic areas to optimize health outcomes.

   While expanding the use of biosimilars in ophthalmology has the potential for substantial health system savings, a founding principle of biosimilar policies must be improving health outcomes for Canadians. Continuous collection of data on pharmacovigilance, adverse reactions and long-term vision health outcomes within the Canadian context will surely provide valuable insights into the impact of biosimilar policies on individuals with blinding eye diseases. As more information becomes available on vision health outcomes in response to the use of lower cost biosimilars in ophthalmology, public savings should be reinvested into patient support programs, clinical research and vision health workforce training.

Conclusion

As biosimilars in ophthalmology rapidly approach patient and advocacy organizations have voiced concerns around the urgent need to address concerns with emerging biosimilar policies pertaining to person-centredness, access and safety. Stakeholders are aligned in proposing key actions that may support the development and implementation of appropriate biosimilar policies in Canada.

However the critical perspective and guidance of vision health care providers is notably absent in the current discourse. Engagement of ophthalmologists is an important next step towards establishing clinical guidelines around the appropriate use of biosimilars in ophthalmology which may align with the ICOPE and IPEC frameworks.

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