the cancer collaborative
le collaboratoire cancer

pan-canadian oncology biosimilars summit
november 12. 2018 toronto ontario

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meeting report prepared by the cancer collaborative

overarching goals

identify stakeholder engagement, quality and safety, evidence informed policy and sustainability and value for money.

stakeholder engagement. collaborate with stakeholders so they participate in the development of a pan-canadian OB strategy.

quality and safety. ensure that OBs are safely implemented and that clinical and patient considerations are taken into account.

evidence informed policy approach. engage pan-canadian partners to discuss pricing, implementation and usage strategies that are informed by the best evidence.

sustainability and value for money. improve system sustainability and performance by facilitating the uptake of OBs and ensuring stakeholders are benefiting from the transition

objectives

“ with the overarching goals in mind [10] strategic objectives were were developed to guide the pan-canadian oncology biosimilars action plan

1. jurisdictions to adopt best practices in prescribing, preparation, labelling, dispensing, and administering biosimilars.

2. technical [eg. IT] challenges of implementing biosimilars should be addressed, as to not limit preferred strategies when implementing biosimilars.

3. Comprehensive education programs for health professionals and patients should be developed.

4. pricing and reimbursement policies are designed, based on best practices, to maximize opportunities for cost-savings. [e.g., drug supply chain risks, market share, etc.].

5. jurisdictions should adopt consistent policies related to pricing and reimbursement for oncology biosimilars.

6. oncology biosimilar implementation strategies should support the overall intent of creating a viable market for biosimilars.

7. develop clear policies regarding clinical scenarios [e.g., initiating, switching, generalizability].

8. cancer systems commit to re-investing savings from oncology biosimilars back into the cancer system.

9. real world evidence should be collected to assess the utilization and confirm the clinical effectiveness and safety of oncology biosimilars.

10. stakeholders to be engaged throughout the project to validate work to date and inform ongoing work.

vision.

stakeholders across canada have implemented an oncology biosimilars strategy that improves outcomes for patients, is evidenced informed, ensures appropriate quality and safety measures are in place, and facilitates access to innovative cancer treatments

accountable stakeholders

CAPCA. cancer agencies. patient advocacy organizations. CADTH [note INESSS and DGC were not included in accountable stakeholders- dominic bélanger was in attendance]

jatinder harchowal from the NHS presented on the UK experience with biosimilars - through the cancer vanguard, the NHS developed a pioneering approach to working with the pharmaceutical industry. the pharma challenge- inviting industry to submit proposals [non-promotional] to optimize biosimilars adoption throughout the UK. [with amgen to map out and measure the most efficient out of hospital administration of denosumab, potentially bringing the treatment closer to patients]

“examples of collaborative and system wide leadership made the pace of delivery of biosimilars possible and consistent throughout the UK

the cancer vanguard partnered with sandoz in a joint working project to share biosimilar knowledge and experience, for the benefit of patients and the NHS. sandoz proposed an education and engagement programme with healthcare professionals across the cancer vanguard about the use of biosimilar medicines. this was done through the development of a central repository of information for the introduction of biosimilars to identify and engage key stakeholders, run education sessions, involve patient groups and develop policies for the introduction of biosimilars.

this example of collaborative and system wide leadership made the pace of delivery of biosimilars possible and consistent throughout the UK

note- the NHS decided to go with an overnight switch to the biosimilar for breast cancer patients, sending out a letter to all affected patients [500 letters were sent out]. it was unclear how much time elapsed between the time the letter was sent out and the switch occurred. only a small handful of patients responded with concerns and one [1] patient refused to get on the biosimilar. the decision to go with an overnight switch was supported by the fact that there was no evidence to suggest that patients already receiving the originator drug would not respond to the biosimilar.

economic implications

market entry price reduction of 15-30% is expected with biosimilars

however, the presence of biosimilars will likely result in competitive decrease in the price of the originator.

clinicians and payors are experienced in deciding whether additional cost is justified based in the additional benefit.

less experience in deciding whether cost saving is justified based on uncertainty about benefit

sustainability of oncology drug budgets

drugs or cancer account for approximately 40% of total cancer care budgets
continued growth in drug spending
- continued development of new drugs
- expanding indications
- use of drugs in combination [note that the cancer collaborative does have an initiative in combination therapies]
- longer duration of therapy [patients living longer was not addressed]
- multiple treatment options in the clinical care pathway

high cost biologic drugs are a large proportion of the drug budget.
rising cost of drugs is unsustainable and affects ability to fund innovative therapies and time to achieve public reimbursement [access issues]

payor perspective

to be successful, need;
- stakeholder confidence and acceptance
- decisions on interchangeability, switching and indications for use
- pricing strategies to maximize discounts, increasing with multiple entrants
- reimbursement and market uptake of biosimilars, including decisions on extrapolation of indications

implementation readiness in the oncology clinic or hospital

readiness will depend on provincial | jurisdictional decisions related to interchangeability, switching and reimbursement indications

if reimbursement | policy decisions allow for use of BOTH biosimilar and the reference biologic drugs [only for a subset of patients, or at the discretion of the physician | patient, or to certain indications] there will be significant resources required to manage integration of biosimilars in the hospital or clinic

payor perspective

reference drug and biosimilar will have the same drug name

- would require update of all paper or electronic preprinted order sets, smart pumps, and pharmacy software to reflect physician prescribing of reference drug or biosimilar trade name.
- trade names are generally not used by clinical management and pharmacy software programs- issues for electronic drug interaction checking and medication history documentation [medical record]
- perpetual staff education and awareness of using non-interchangeable drug products with the same name- outside the norm of hospital | clinic

increase in purchasing and inventory workload

- stocking multiple brands of the same drug makes it difficult to predict inventory levels required
- each new drug purchased and stocked by pharmacy generates new purchase order and invoice payment workload.

“ need for stakeholder[s] confidence and acceptance

increase in storage requirements

- stocking multiple brands of the same drug all requiring refrigeration will create need for more alarmed, pharmaceutical refrigerators- will there be physical space and budget for more refrigerators.

need to change labelling procedures for drug prescriptions to identify drug by trade name instead of generic drug name

increased risk of medication errors- risk of choosing the ‘wrong brand’ for a patient, which would be a drug error of not deemed interchangeable or if used for an indication where only the reference biologic is ‘approved’.

increased drug wastage- reduce cost savings we are trying to achieve with a lower costs biosimilar

- no opportunity for vial sharing among different brands of the same drug
- ‘wrong drug product’ chosen for mixing- need to waste and re-make

“ need for a consistent approach and messaging to patients

need to accurate systems of tracking which drug product was received by patients for adverse event reporting

need for a consistent approach and messaging to patients

- what should be the requirements for patient information and education?
- what changes need to be made to patient education | consent discussion?
- what type of discussion is necessary with patients? is it different for a new patient then one who is on treatment or had been treated before?
- how to manage different perspectives about biosimilars among health care providers and how this perspective would be transitioned to patients?

summary- payor & system perspectives

successful integration of biosimilars into clinical practice is extremely important to realize cost savings

decisions on a strategy for biosimilar adoption must carefully consider capacity for implementation in the health system

participants were divided into six groups to work on the strategic objectives - [group three worked on strategic objectives four, five and six]. each group was given a set of objectives and questions. after an hour of discussion each group reported back.

CCO and pCPA will be sharing a report back of each groups discussion.

a participants list was not shared among delegates however it included hospital pharmacists, rheumatologists, patient advocacy groups [besides durhane wong-reiger no non-oncology groups with experience with biosimilars were invited], oncologists, CCO, pCPA, CADTH, payors [private and public]

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innovation+
collaboration
= change