APPENDIX 1 (Part 1 of 3). Biosimilars Implementation Evaluation Framework.

RE-AIM Element	Evaluation Questions	Indicators	Data Collection[a]
Stakeholder engagement			
Reach	Which stakeholders were invited to participate, and were they representative of the affected parties?	Number and list of invited stakeholders	Organizational
	Who was engaged in developing the funding policies, and to which groups were these policies communicated?	Number and types of stakeholders involved in the development of funding policies	Organizational
		Intended recipients of communicated funding policies	Organizational
Effectiveness	Do stakeholders believe their contributions were valued, making them champions of the work?	How and when stakeholders were engaged	Qualitative
		How stakeholder input was used	Qualitative
		Stakeholders' perceptions of their contributions	Qualitative
Adoption	What influenced the development of the funding policies (e.g., evidence, rationale, other jurisdictions' experience, effect of private sector policies)?	Resources, evidence, reports, and stakeholder feedback used to develop funding policies	Qualitative
Maintenance	What changes were made to funding policies after initial implementation?	Changes made to the funding policy after its initial release	Qualitative
Patient experience			
Reach	Who was targeted for biosimilar education?	Types of individuals targeted for biosimilar education	Organizational
		Patient groups not targeted or missed for biosimilar education	Qualitative
Effectiveness	Were there unintended outcomes of the funding policies?	Change in travel distance to treatment site after switching to a biosimilar	Qualitative
		Change in patient out-of-pocket expenses after switching to a biosimilar	Qualitative
	Did educational resources increase knowledge and acceptance of biosimilars?	Percent of individuals who indicated increased knowledge after receiving education about biosimilars	Qualitative
Adoption	How were educational resources accessed and used (by format and by stakeholder group)?	Number of individuals who accessed each type of educational resource	Organizational
Patient outcomes			
Effectiveness	Were there unintended outcomes of the funding policies?	Number of outpatient physician visits compared with historical cohorts	Administrative
		Number of hospitalizations compared with historical cohorts	Administrative
		Number of emergency department visits compared with historical cohorts	Administrative
		Use of concomitant drug products after a switch to a biosimilar, compared with historical cohorts	Administrative
		Discontinuation rates of a biosimilar, compared with historical cohorts on the reference biologic	Administrative
		Number of patients switching back to the reference biologic after switching to the biosimilar	Administrative

Appendix to: Milgram L, Wheeler S, Adamic A, Loncar M, Guirguis M, McCabe BJ. A framework for evaluating the implementation of biosimilar drugs. *Can J Hosp Pharm*. 2023;76(2):109-16.

APPENDIX 1 (Part 2 of 3). Biosimilars Implementation Evaluation Framework.

RE-AIM Element	Evaluation Questions	Indicators	Data Collection[a]
Clinician experience			
Reach	Which individuals (roles, groups) were targeted in preparation for local implementation (i.e., at hospitals/clinics and other care settings) of biosimilars? How?	Activities used to implement biosimilars on the front lines of care (e.g., information system upgrades, education delivery, revisions to policies and procedures)	Qualitative
		Resources required for implementation of biosimilars (e.g., time, money, human resources)	Qualitative
Effectiveness	Did educational materials increase knowledge and acceptance of biosimilars?	Percent of clinicians who indicated increased knowledge after receiving education about biosimilars	Qualitative
		Patients who were switched to a new therapeutic class instead of being switched to a biosimilar	Administrative
Adoption	What enablers or barriers affected biosimilar implementation at the local level (e.g., stakeholders, existing information systems, existing practices/operations, available staff)?	Enablers and barriers to local implementation	Qualitative
		Gaps that were identified and supports that were needed during implementation	Qualitative
	Who was targeted for biosimilar education?	Types of clinicians targeted for biosimilar education	Organizational
		Clinicians not targeted or missed for biosimilar education	Qualitative
	How were educational resources accessed and used (by format and by stakeholder group)?	Number of clinicians who accessed the educational resources	Organizational
Implementation	What changes were made at the local level to integrate biosimilars?	Changes in physician time for each patient switched to a biosimilar	Qualitative
		Changes in nursing time for each patient switched to a biosimilar	Qualitative
		Changes in pharmacist time for each patient switched to a biosimilar	Qualitative
		Changes in administrative time for each patient switched to a biosimilar	Qualitative
		Work effort for initial and subsequent biosimilar drug implementations by type of activity (e.g., clinician education, system upgrades, policy and procedure revisions, patient education, administrative requirements for switching a patient to a biosimilar)	Qualitative
		Number of new and existing FTE resources dedicated to initial and subsequent biosimilar drug implementations	Qualitative
		Timelines for initial and subsequent biosimilar drug implementation	Qualitative
		Readiness of data collection systems to collect biosimilar data	Qualitative
		Changes that were made to existing systems to support data collection with respect to biosimilars	Qualitative
	How were educational materials incorporated into clinical practice?	Ways in which materials were incorporated into practice (e.g., protocols updated, links to materials on website, placement of printed materials in clinics, training requirements)	Qualitative
Maintenance	What administrative and clinical supports are in place to ensure the ease of ongoing use of biosimilars?	Types of resources in place to support new biosimilar implementations at treatment facilities	Qualitative

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APPENDIX 1 (Part 3 of 3). Biosimilars Implementation Evaluation Framework.

RE-AIM Element	Evaluation Questions	Indicators	Data Collection[a]
System sustainability and affordability			
Effectiveness	What were the intended outcomes or targets of the funding policies?	Utilization of biosimilars	Administrative
		The extent to which utilization targets were achieved	Administrative
	Were they reached, and after how long?	Utilization of related drugs (e.g., concomitant drugs, different therapeutic classes)	Administrative
	Did different funding policies lead to different outcomes in the uptake of biosimilars?	Number of jurisdictions that have an exception policy or process	Organizational
		Number of exception requests received	Administrative
		Approval rate of exception requests	Administrative
		Cost savings within a defined time period after implementation	Administrative
		Market distribution of brands for a drug	Administrative
		Administrative resources required for multiple brand negotiations and contracting	Qualitative
		Number of amendments to product listing agreements	Organizational
		Timing of jurisdictional funding of new biosimilar drugs after regulatory approval or price negotiation	Organizational
		Change in utilization of health care resources	Qualitative

FTE = full-time equivalent.

[a]Organizational data consist of information about how a program is constructed and operates, which is used to understand how a program is implemented. Qualitative data consist of information about context, which is used to understand why a program worked well or did not work well. Administrative data consist of information routinely collected about program operations, which is used for performance management, funding, or reporting.

Appendix to: Milgram L, Wheeler S, Adamic A, Loncar M, Guirguis M, McCabe BJ. A framework for evaluating the implementation of biosimilar drugs. *Can J Hosp Pharm*. 2023;76(2):109-16.