Development of a Provincial Hospital Drug Formulary from 12 Former Regional Health Authority Formularies: Methods of Alignment

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INTRODUCTION

In 2017, the Saskatchewan Health Authority (SHA) was formed through the amalgamation of 12 former regional health authorities (fRHAs).[1] The purpose of the merger was to coordinate services across Saskatchewan and facilitate continuity of care for residents, regardless of their location within the province.[1]

Saskatchewan's hospital system represents one of only a few merged Canadian systems. Other amalgamated systems, such as Alberta Health Services and the New Brunswick Regional Health Authorities, were consulted for guidance in development of the SHA formulary system. A formulary system refers to the multidisciplinary process that organizations use to provide evidence-based, safe, and cost-effective drug therapy to patients.[2] An integral part of a formulary system is the drug formulary. This list of the drugs used in the diagnosis, prophylaxis, or treatment of conditions is based on research evidence, the clinical judgment of health experts, and patient values.[2] The involvement of health care providers from various disciplines in the development of a formulary allows organizations to make interprofessional decisions regarding drug use.[2]

Amalgamating the fRHAs involved unifying systematic processes, including the alignment of pre-existing drug formularies. This required the implementation of formulary system management from a multihospital perspective that would contribute to standardization of the formulary.[3] All participants in the drug-use system, including frontline clinicians, pharmacists, and nurses, have a responsibility to promote rational drug use that is evidence-based, safe, and effective. These participants stand to benefit from a formulary system that manages risks and assesses pharmacoeconomic value.[4] A well-designed system is integral to allowing pharmacy to control inventory and guide prescribers in selecting appropriate drugs.[5] To represent the needs of various disciplines and patients, an interprofessional committee is required to manage the formulary system.

DEVELOPMENT AND ONGOING MANAGEMENT OF SHA DRUG FORMULARY SYSTEM

Given that the SHA represents a multihospital system, the process of establishing not only the drug formulary but also the Drugs and Therapeutics Committee (DTC) had to represent the needs of the individual SHA facilities; this concept is the principle for successful formulary integration.[2] The SHA DTC was formed in 2021, replacing the fRHAs' pharmacy and therapeutics committees. The purposes of the DTC are the development, implementation, maintenance, and communication of a formulary with evidence-informed, safe, and cost-effective drug products, policies, and procedures.

The members of the SHA DTC are appointed by the Provincial Practitioner Advisory Committee and the SHA executive leadership team. The cochairs of the DTC are the director of patient care and performance, from Pharmacy Services, and the pharmacy physician lead. There is a maximum of 30 voting members on the DTC, drawn from urban and rural centres and consisting of 40% physicians, 30% executive directors or directors, 15% pharmacists, 15% nurses, and a patient family partner. Decisions can be made during DTC meetings only if a majority of members are present as quorum. Several specialized committees report directly to the DTC, specifically the Medication Use and Safety Interdisciplinary Committee – Steering Committee, the Antimicrobial Advisory Subcommittee, the Pediatric Advisory Committee, and the Saskatchewan Poison Information Services Advisory Committee. The DTC is accountable to the provincial programs physician executive and the chief medical officer (for the DTC reporting structure, see Appendix 1).

The DTC is a decision-making body for formulary management within the SHA, authorized to approve the

addition of any drug with an estimated maximum annual cost of $200 000. Recommendations for drugs with an estimated cost per drug exceeding $200 000 annually are submitted to the executive leadership team for further review. Most drugs are added to the SHA Drug Formulary through the alignment process, and drugs with new indications or drugs that are newly marketed are added through the "drug review for addition to formulary process". This process is guided by a standardized formulary evaluation prepared by SHA Pharmacy Services when a request or "trigger" for addition is established. The prespecified triggers are addition to the outpatient formulary available to most Saskatchewan residents, referred to as the Saskatchewan Drug Plan (SDP) Formulary, and nonformulary drugs that have been prescribed in any SHA facility 5 times or more in the previous 3 months. Pharmacy Services personnel complete the initial evaluation, which then is reviewed by the DTC according to an assigned priority category. High-priority reviews are conducted for unique drug classes with a significant impact on morbidity and mortality, and these high-priority reviews take place at the next available DTC meeting. The evaluation takes into account efficacy, safety, cost, minimization of duplicate drug molecules within the formulary, current utilization, guideline recommendations, need for restrictions or criteria for use, status on outpatient formularies, SHA priorities, and practical considerations.

The inclusion of outpatient considerations in the evaluation allows the SHA to coordinate inpatient and outpatient formularies. This approach improves patients' access to drugs while they are admitted to hospital and helps ensure continuity of treatment at transitions of care.[3] The main outpatient formulary that the DTC considers is the SDP Formulary. The SHA Drug Formulary also takes into account other outpatient formularies, such as the Non-Insured Health Benefits Program; however, it does not create formulary guidelines for oncology drugs, because a separate formulary for these agents is managed by the Saskatchewan Cancer Agency.

To further coordinate services, allocate resources, and set standards of care across facilities, the SHA has created Tiers of Service. These tiers, which influence service distribution, range from Tier 1, representing the service needs available in every facility, to Tier 6, which represents specialized services available only in a limited number of selected facilities.[6] The existing formularies of the larger Tier 5 and Tier 6 facilities (i.e., the former Saskatoon Health Region and the former Regina Qu'Appelle Health Region) strongly influence the formulary alignment process.

METHODS OF ALIGNMENT

The process of amalgamating the fRHA formularies consisted of 3 phases: an environmental scan and gap analysis, application of guiding principles for formulary alignment, and a review of selected drugs by the Formulary Alignment Working Group to assess their suitability for formulary inclusion. The Formulary Alignment Working Group consists of pharmacist leadership representing different regions in the province. The application of these methods generated recommendations on the inclusion or exclusion of drugs on the SHA Drug Formulary, which were presented to the DTC for review.

The environmental scan and gap analysis, phase 1, initiated the alignment process by examining the drugs and restrictions for use listed on each fRHA formulary. Although the American Hospital Formulary Service (AHFS) classification is no longer recognized by Health Canada, the drugs were reviewed according to this classification because it is widely used and readily accessible.[7] Each drug was assessed at the drug molecule level, not on the basis of drug identification number. Furthermore, biosimilar drugs were reviewed in terms of the originator product; processes for use of these agents are still under development. After consultation with pharmacy managers and directors across the SHA, it was decided to include strength and package size within the SHA Drug Formulary, but site-specific stock is determined by local pharmacy departments.

In phase 2, guiding principles were developed to allow systematic alignment of the fRHA formularies. Before this phase was initiated, the previous formulary management processes used by the fRHAs were assessed. Because they all had evidence-based formulary systems, it was deemed unnecessary to re-review AHFS classes or individual drugs previously assessed by an fRHA. The guiding principles implemented drug- and policy-specific guidelines (Table 1 and Table 2) for amalgamating the formularies.

Following phase 2, drugs that met the inclusion criteria were presented to the DTC for final approval. Drugs not meeting the inclusion criteria were reviewed by the Formulary Alignment Working Group. This group assessed restriction discrepancies among the fRHA formularies, drugs with low provincial utilization, and drugs intended for long-term outpatient use that are not listed on the SDP Formulary. Clinical experts were consulted and the literature was reviewed as needed. The recommendations of the Formulary Alignment Working Group are reviewed for approval by the DTC.

The SHA must have procedures for ongoing revision of the formulary. More specifically, the SHA Drug Formulary is to be maintained with a standardized process for adding and removing drugs that reflects clinical judgment, research evidence, and patient values; finalization of these policies is in progress. Final decisions on formulary status are authorized by the DTC, and it is therefore this committee that is responsible for formulary maintenance.

EVALUATION OF DTC PERFORMANCE

Defined procedures outlining the evaluation of drugs for addition to the SHA Drug Formulary were already

in existence, so an evaluation process was developed to ensure that drugs are reviewed within the assigned priority timeline, to ensure timely communication strategies, and to assess the financial impact on the SHA. The DTC's metrics data are collected each quarter and are reported by SHA Pharmacy Services at year-end to the DTC and to the provincial programs physician executive and chief medical officer. These metrics include the proportion of drug evaluations presented to the DTC within assigned review timelines, characterization of final DTC recommendations, the financial impact of DTC decisions, the proportion of recommendations requiring review by the executive leadership team, and whether initial recommendations created by SHA Pharmacy Services were approved or required amendments. Characterization of amendments is not included as a metric. Additional metrics include the proportion of drug formulary recommendations accepted, the source of feedback affecting the recommendation, the total number of requests for formulary additions received in each priority category, and post-meeting communication within specified timeframes.

CONCLUSION

The purpose of amalgamating the fRHAs was to ensure the coordination of operations and equitable access to care for patients across Saskatchewan.[1] Consolidating various formularies will standardize the criteria for use of individual drugs and will act as a decision support tool to promote consistency in practice for clinicians and continuity of care for patients throughout SHA facilities.[8]

TABLE 1. Guiding Principles for Formulary Alignment: Drug-Specific Guidelines for Management

Drug-Specific Guideline for Management	Decision
Drugs listed in the majority (≥ 6) of fRHA formularies, one of which is either fSHR or fRQHR	Include on formulary
Drugs listed on formularies of both fSHR and fRQHR and, where applicable, criteria to align are provided	Include on formulary
Antiretrovirals, anticonvulsants, and antirejection drugs listed on the SDP Formulary and alignment with SDP Formulary criteria	Include on formulary
All drugs listed in the antidote stocking guidelines of the Saskatchewan Poison Information Services Advisory Committee	Include on formulary
If a drug intended for long-term outpatient use is listed on one of the fRHA formularies but is not listed on the SDP Formulary, then the CDR recommendations made by CADTH will be reviewed	
CADTH recommends not listing the drug on a formulary, or CADTH has not yet completed a CDR for the drug	Forward to Formulary Alignment Working Group
CADTH recommends listing the drug, with conditions for use, on a formulary	Forward to Formulary Alignment Working Group
CADTH recommends listing the drug on a formulary	Include on formulary

CADTH = Canada's Drug and Health Technology Agency, CDR = Common Drug Review, fRHA = former regional health authority, fRQHR = former Regina Qu'Appelle Health Region, fSHR = former Saskatoon Health Region, SDP = Saskatchewan Drug Plan.

TABLE 2. Guiding Principles for Formulary Alignment: Policy-Specific Guidelines for Management

Policy-Specific Guideline for Management	Decision
Significant discrepancies between formularies in terms of restriction criteria, as determined by the pharmacy assessor	Forward to the Formulary Alignment Working Group
Drugs on fRHA formulary that are no longer available	Forward to the Formulary Alignment Working Group
Consideration of historical usage, specifically for drugs with < 500 units of an individual dosage form per year	Forward to the Formulary Alignment Working Group
Where applicable, the SHA Drug Formulary will align with SDP Formulary restrictions to promote continuity of care	Decision to list will depend on the following: • need for use in SHA facilities • market share in the community • cost and ability to achieve significant cost savings
Strength and package sizes not specified on fRHA formularies	When not specified, individual pharmacy department locations will decide which strength and package size to stock for a given drug and dosage form

fRHA = former regional health authorities, SDP = Saskatchewan Drug Plan, SHA = Saskatchewan Health Authority.

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APPENDIX 1: The reporting structure of the Drugs and Therapeutics Committee, Saskatchewan Health Authority, as of January 2023.