A READY-TO-USE LIQUID GLUCAGON RESCUE PEN FOR SEVERE HYPOGLYCEMIA DEMONSTRATES REDUCED HEALTHCARE PAYER COSTS IN A BUDGET IMPACT MODEL

Brian Leinwand PhD[1], Michael Johnsrud PhD[1], Anh Nguyen MD[2], Ken Johnson PharmD[2]
[1]Avalere Health; [2]Xeris Pharmaceuticals

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ABSTRACT

BACKGROUND: A ready-to-use, room-temperature stable liquid glucagon rescue pen auto-injector (GRP; Xeris Pharmaceuticals) has been developed for the rescue of severe hypoglycemia events (SHEs). GRP has a simple two-step process to administer of a full dose of glucagon, where in a simulated emergency setting 99% of users successfully (high functional efficacy). Conversely, in marketed glucagon emergency kits (GEK) only 0% to 31% of users were successful.

OBJECTIVE: Model the annual value of GRP compared to GEK or no glucagon for SHE rescue treatment in people with diabetes.

METHODS: To estimate the economic impact of a GRP, we developed a one-year budget impact model from a US commercial health plan perspective. Cost offsets from successful glucagon administration incorporated EMS, ED, inpatient, and outpatient utilization. Diabetes prevalence and event probabilities were estimated from publicly-available sources. Costs ($ USD) were obtained from the 2018 Medicare Fee Schedules and adjusted to represent commercial payer costs.

RESULTS: GRP led to fewer EMS, ED, inpatient, and outpatient costs compared to GEK and no kit, resulting in total per-patient SHE costs of $2,564, $3,606, and $3,849, respectively. Health plan costs for one million covered lives were almost $9 million compared to $8.2 million following introduction of GRP.

CONCLUSIONS: The functional efficacy of GRP virtually eliminates user errors and may reduce utilization of emergency medical services (EMS), emergency department (ED), and overall inpatient and outpatient costs for SHE. A budget impact model suggests significant annual cost savings for US commercial payers can be achieved with GRP.

BACKGROUND

Hypoglycemia is highly feared by persons with diabetes (PWDs) and can lead to coma, seizures, and automobile accidents. Currently approved glucagon emergency kits (GEKs) for severe hypoglycemia rescue are based on lyophilized formulations that require manual reconstitution with a vial and syringe at time of use, and thus are difficult to administer and not well accepted by users. A ready-to-use, room-temperature stable liquid glucagon rescue pen auto-injector (GRP; Xeris Pharmaceuticals) has been developed for the rescue of severe hypoglycemia events (SHEs). GRP has comparable clinical efficacy to GEKs and utilizes a simple two-step process to administer of a full dose of glucagon, where in a simulated emergency setting 99% of GRP users successfully delivered a full dose of glucagon. Conversely, in marketed GEKs only 0% to 31% of users were successful.

GLUCAGON EMERGENCY KIT (STANDARD OF CARE) HAS ADMINISTRATION CHALLENGES

- Drug mixed at time of use[1]
- Limited stability in solution[1]
- Nine steps to injection[1]
- 1 ml intramuscular injection[1]
- Many possible failure modes[2]
- Creates fear & anxiety[2]
- Poor user experience[2]
- Requires dosing measurement for pediatric vs. adult dose

[1]GlucaGen® (glucagon [rDNA origin] for injection) Hypokit® Instructions for Use. Novo Nordisk A/S. 25 April 2014.

[2]XSGP-HF02 Study Report. Xeris Pharmaceuticals, Inc. 26 March 2015.

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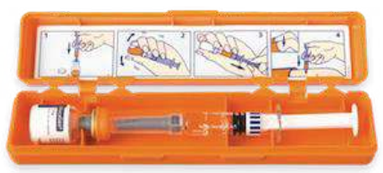

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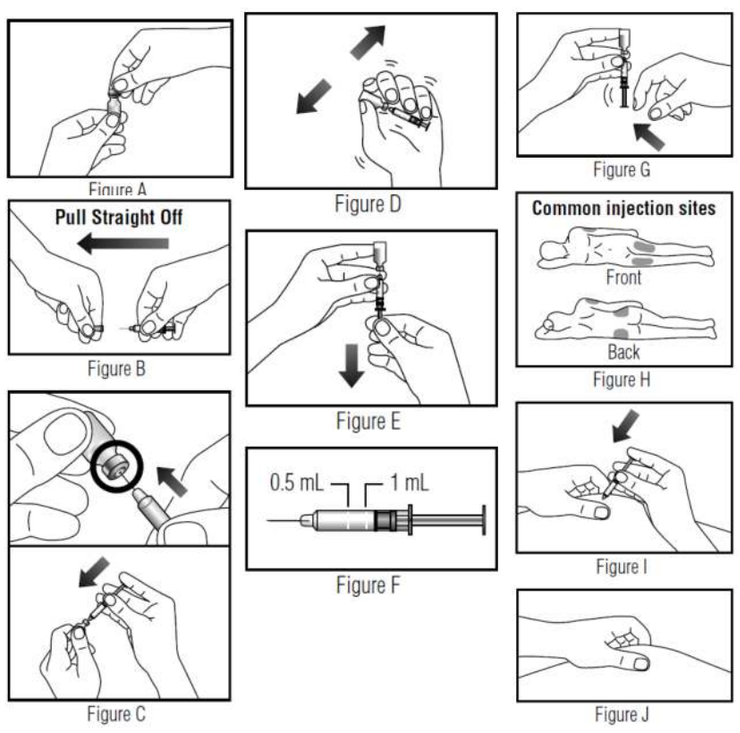
*GLUCAGON EMERGENCY KIT INSTRUCTIONS FOR USE**

9-step reconstitution process could be challenging in an emergency situation

*GlucaGen® (glucagon [rDNA origin] for injection) Hypokit® Instructions for Use. Novo Nordisk A/S. 25 April 2014.

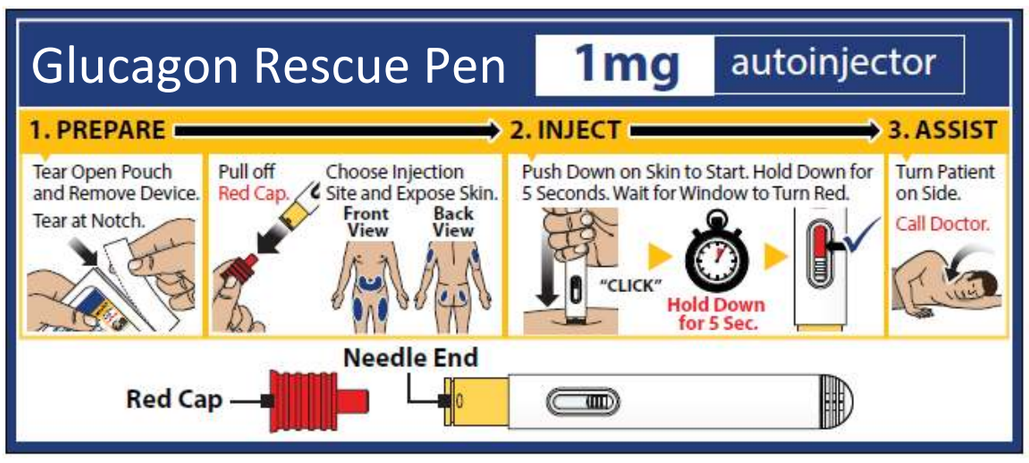


GLUCAGON RESCUE PEN (GRP)

- Pre-mixed solution in SHL Molly auto-injector
- Long-term stability in solution at room temperature[1]
- 0.2 ml subcutaneous injection
- Easy, rapid injection[2]
- Reduces fear & anxiety[2]
- User-friendly[2]

[1]Newswanger B, Ammons S, Phadnis N, et al. Development of a highly stable, nonaqueous glucagon formulation for delivery via infusion pump systems. *J Diabetes Sci Tech.* 2015;9:24–33.

[2]XSGP-HF02 Study Report. Xeris Pharmaceuticals, Inc. 26 March 2015.



OBJECTIVE

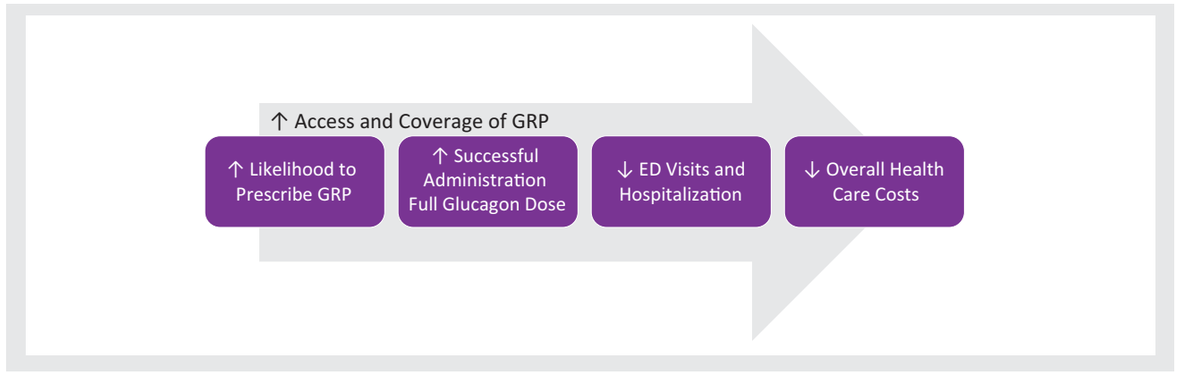
Based upon relevant scenarios that consist of a set of specific assumptions and other health characteristics, the annual value of GRP was modeled in a commercial health plan in comparison to GEK or no glucagon for the rescue treatment of SHEs in persons with diabetes.

Complement cost-offset analyses were performed with an evaluation of the budget impact of introducing GRP to the market, modelling:

- Populations with insulin-treated diabetes, a population who is at increased risk of SHEs
- Time horizon of 1 year
- Treatment success and cost data
- Perspective of a commercial health payer to cover 1M lives

The GRP is hypothesized to decrease costs through improved ease of use.

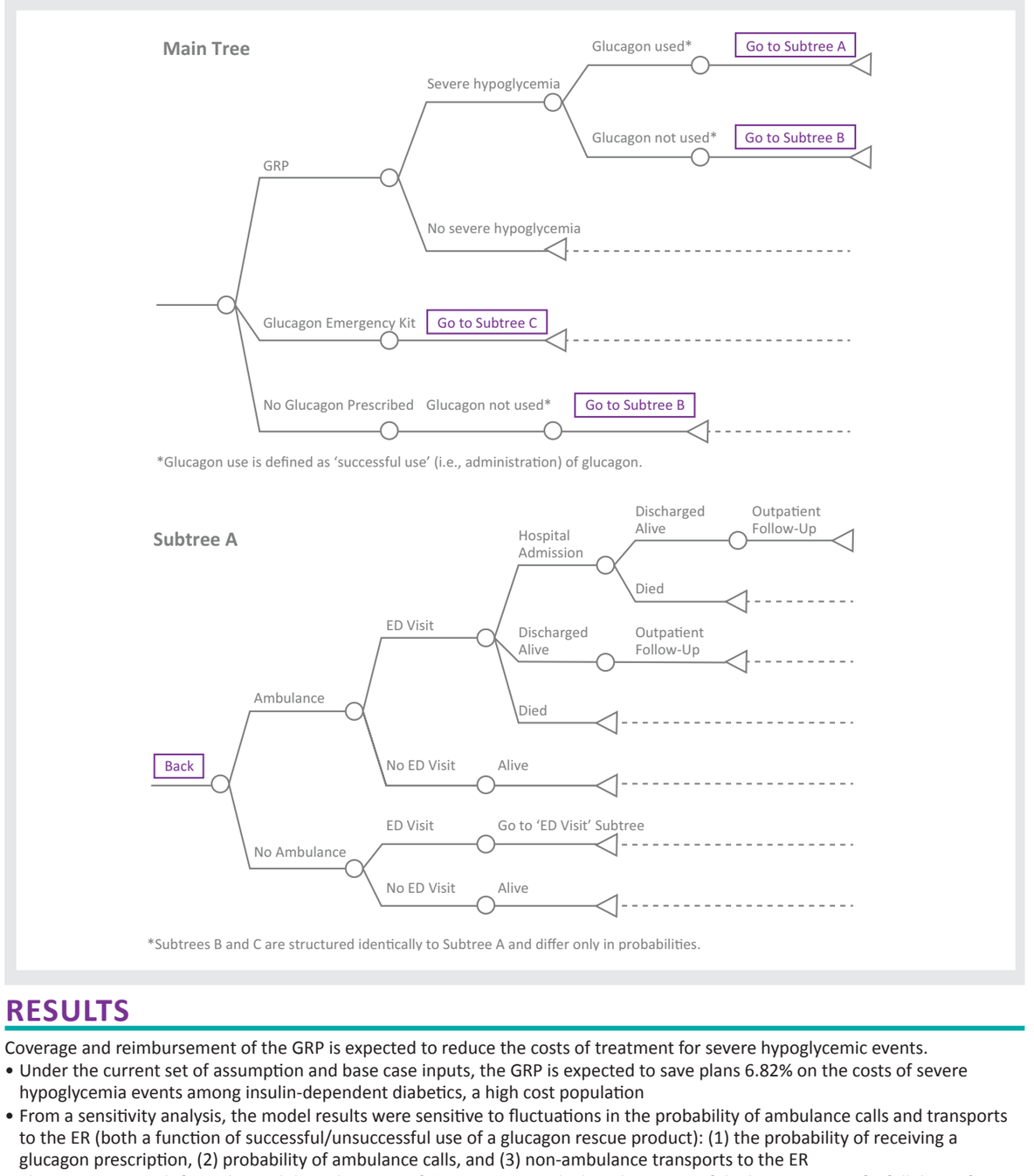
Improved Access to Glucagon Decreases the Need for Further Health Resource Use



METHODS

- The budget impact model is based on US cost data and SHE treatment pathways
- The model was populated with data from various sources:
  - Peer-Reviewed Medical Literature
    - Database reviewed: MEDLINE (PubMed)
    - Study population: humans
    - Time period: 2004 - 2014
    - Language: Published in English
  - Medicare Fee Schedule
    - Costs for health care resource use were obtained from the Medicare Fee Schedule and inflated to represent the typical US private payer
- The GRP Cost-offset and Budget Impact Model was developed to model
  - Per-SHE cost-offset of GRP versus GEK or no glucagon from commercial health care payer perspective when covering 1M lives
  - Combine cost-offset with population-specific SHE incidence and morbidity/mortality data as well as market share projections to yield the budget impact of GRP
  - The budget impact was assessed for scenarios where PWDs have GEK or no kit ("current state"), and when PWDs have GEK, no kit, or GRP ("new state")
    - Base case assumption: GRP will acquire 20% of the GEK market and 25% of the no glucagon market

Budget Impact Model Based Upon SHE Treatment Pathway



RESULTS

Coverage and reimbursement of the GRP is expected to reduce the costs of treatment for severe hypoglycemic events.

- Under the current set of assumption and base case inputs, the GRP is expected to save plans 6.82% on the costs of severe hypoglycemia events among insulin-dependent diabetics, a high cost population
- From a sensitivity analysis, the model results were sensitive to fluctuations in the probability of ambulance calls and transports to the ER (both a function of successful/unsuccessful use of a glucagon rescue product): (1) the probability of receiving a glucagon prescription, (2) probability of ambulance calls, and (3) non-ambulance transports to the ER
- These savings result from the usability advantage of GRP over GEK, which makes successful administration of a full dose of glucagon, by caregivers, during SHEs more likely
- GRP is likely to represent a valuable, treatment cost-effective rescue therapy for SHEs in the U.S., particularly in populations with insulin-treated diabetes at increased risk of frequent SHEs

Projected Health Care Costs Associated with Successful and Unsuccessful Glucagon Use, per SHE

	Successful Glucagon Use	Unsuccessful Glucagon Use
Ambulance	$304	$413
Emergency Department Visit	$834	$1,433
Hospitalization	$571	$981
Total	**$1,709**	**$2,827**

Base Case Results For a Plan with 1,000,000 Covered Lives

Outputs	Before GRP	After GRP
Total Annual Plan Costs for Severe Hypoglycemic Events	$5,865,416	$5,465,681
Annual Costs per Diabetes Patient	$270.60	$252.16
Cost per Diabetes Patient per Month	$22.55	$21.01
Annual Cost per Member	$5.87	$5.47
Cost Per Member Per Month	$0.49	$0.46
Reduction in Total Plan Costs	—	**6.82%**

CONCLUSIONS

GRP allows for easier administration of glucagon by caregivers of persons with diabetes who experience severe hypoglycemia and improves the successful administration of a full dose of glucagon. The usability advantage of GRP over marketed GEKs virtually eliminates user errors and may further reduce utilization of emergency medical services, emergency department, overall inpatient and outpatient costs for SHE, and potentially reduce mortality. Introducing GRP to the market is likely to reduce the budget a commercial health care payer spends across the entire SHE treatment pathway. Our budget impact model suggests that significant overall annual cost savings for U.S. commercial payers can be achieved with GRP.

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