Healthcare Provider (HCP) Experiences with Gemcitabine Intravesical System in Non-Muscle Invasive Bladder Cancer: A Qualitative Study of SunRISe Trial Investigators

Authors:

[1]Joshua Meeks, MD, PhD; [2] Dee Lin, PharmD, MS; [2] Eliza Raymundo, MD, DMCC; [2] Thushani Siriwardhane, PhD; [3] Timothy Lyon, MD; [2] Lucy Andersen, PhD, OCN, RN; [4] Claire Kavanagh, PhD; [5] Michael Kelleher, PhD; [6] Priyanka Madireddi, PhD; [6] Kruti Joshi, MPH; [7] Meaghan Roach, MPH; [7] Richard Murphy, BA; [7] Cory Williams, MPA; [8] Alex Filicevas, MA; [9]Petros Grivas

Affiliations:

[1] Northwestern Medicine Urology, Chicago IL USA; [2] Johnson & Johnson, Raritan, NJ USA; [3] Mayo Clinic Florida Hospital, Department of Urology, Florida USA; [4] Johnson & Johnson, Dublin, Ireland; [5] Johnson & Johnson, High Wycombe, United Kingdom; [6] Johnson & Johnson, Horsham, PA; [7] Precision AQ, Evidence Solutions, Boston, MA USA; [8] World Bladder Cancer Patient Coalition Brussels, Belgium; [9] Fred Hutch Cancer Center, University of Washington School of Medicine, Seattle, WA, USA.

Key Takeaways

Findings indicate that the insertions and removals of Gem-iDRS are generally perceived as straightforward, efficient, and feasible across various clinical settings, as reported by the HCPs and AHCPs participating in the trial.

Trial investigators considered Gem-iDRS to be better tolerated, with local and mild adverse events, and less time-consuming than other intravesical treatments, including BCG and chemotherapy.

Findings complement the previously reported clinical trial data and suggest that Gem-iDRS could offer a treatment approach that is both patient- and provider-friendly.

Conclusions

This is the first study exploring HCP and AHCP experiences of Gem-iDRS for NMIBC*.

Alongside clinical trial data, results from this qualitative study support that Gem-iDRS could address unmet needs in NMIBC* by providing a novel therapeutic option that improves experience of HCPs and patients.

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Poster

Narrated poster video

Supplementary material

https://www.congresshub.com/Oncology/SUO2025/TAR-200/Meeks

Disclosures

Joshua Meeks, MD, PhD, Consulting or Advisory Role – Johnson & Johnson; Dee Lin, PharmD, MS, Employee of Johnson & Johnson; Eliza Raymundo, MD, DMCC, Employee of Johnson & Johnson; Thushani Siriwardhane, PhD, Employee of Johnson & Johnson; Timothy Lyon, MD, Consulting or Advisory Role – Johnson & Johnson; Lucy Andersen, PhD, OCN, RN, Employee of Johnson & Johnson; Claire Kavanagh, PhD, Employee of Johnson & Johnson; Michael Kelleher, PhD, Employee of Johnson & Johnson; Priyanka Madireddi, PhD, Employee of Johnson & Johnson; Kruti Joshi, MPH, ended employment with Johnson & Johnson in last 12 months; Meaghan Roach, MPH, Ended employment with Precision AQ in last 12 months, Current employee of AbbVie, Research Funding – Johnson & Johnson; Richard Murphy, BA, Employee of Precision AQ, Research Funding – Johnson & Johnson; Cory Williams, MPA, Employee of Precision AQ, Research Funding – Johnson & Johnson; Alex Filicevas, Consulting or Advisory Role – Johnson & Johnson, Petros Grivas, Consulting with MSD, Bristol Myers Squibb, AstraZeneca, EMD Serono, Pfizer, Janssen, Roche, Astellas Pharma, Gilead Sciences, Strata Oncology, AbbVie, Bicycle Therapeutics, Replimune, Daiichi Sankyo, Foundation Medicine, Eli Lilly, Urogen, Tyra Biosciences, and research funding from Bristol-Myers Squibb, MSD, EMD Serono, Gilead Sciences, Acrivon Therapeutics, ALX Oncology, Genentech (paid to institution).

Introduction

- Gemcitabine intravesical system (Gem-iDRS) is a novel intravesical gemcitabine therapy that has recently been approved by the FDA for BCG-unresponsive NMIBC with carcinoma in situ with or without papillary tumors and is under investigation for additional indications, including BCG-naïve HR-NMIBC and BCG-experienced HR-NMIBC.
- Results from the SunRISe-1 phase 2b trial demonstrate a favorable safety profile and durable complete responses with Gem-iDRS monotherapy, addressing a significant unmet need for patients who are ineligible for or who decline radical cystectomy.
- This study aims to qualitatively understand the treatment experiences and clinical practices of trial investigators, which could inform future clinical practice and enhance the management of patients treated with Gem-iDRS for NMIBC.

Methods

- Healthcare providers (HCPs) specializing in urology who participated in the SunRISe-1 or SunRISe-3 trials in the United States and allied healthcare professionals (AHCPs) who assisted these HCPs during SunRISe trials were invited to participate in virtual, 60-minute, semi-structured, open-ended, 1-on-1 qualitative interviews between April and June 2025.
- Interviews elicited HCPs' practices in Gem-iDRS preparation, insertion, removal, monitoring, management of adverse events (AEs), care model designs, and their perceived future practice patterns with Gem-iDRS in a real-world (RW) setting.
- The study sponsor was blinded to the identity of the HCPs and AHCPs included in the research.
- Interviews were audio-recorded, and transcripts were coded using NVivo qualitative data analysis software.
- Results were analyzed in aggregate and summarized descriptively.

Results

Participants

- 18 HCPs representing unique trial sites from 13 states completed interviews.
- 6 AHCPs representing 5 practices, some from the same practice sites as the HCPs, across 5 states completed interviews.

Table 1: Participant Characteristics

Characteristic	HCP (N=18 (%))	AHCP (N=6 (%))
Gender		
Male	17 (94.4%)	1 (16.7%)
Female	1 (5.6%)	5 (83.3%)
Race		
White or Caucasian	15 (83.3%)	6 (100%)
Asian	1 (5.6%)	0 (0%)
Other or prefer not to answer	2 (11.1%)	0 (0%)
Ethnicity		
Not Hispanic, Latino, or Spanish origin	16 (88.9%)	1 (16.7%)
	2 (11.1%)	4 (66.7%)
Prefer not to answer	0 (0%)	1 (16.7%)
Geographic setting		
Urban	12 (66.7%)	3 (50.0%)
Suburban	6 (33.3%)	3 (50.0%)
Practice setting		
Community	12 (66.7%)	6 (100%)
Academic	6 (33.3%)	0 (0%)

Figure 1: Participant Location

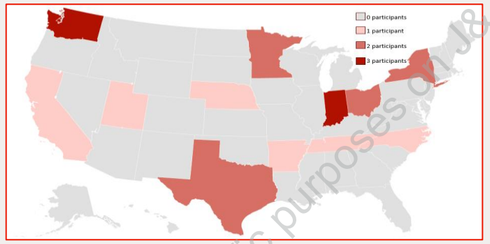

Table 2: HCP Experience

Characteristic	N=18 (%)
Years in practice	
5 years or less	1 (5.6%)
6-10 years	5 (27.8%)
11-15 years	3 (16.6%)
16-20 years	3 (16.6%)
More than 20 years	6 (33.3%)
Patients treated with Gem-iDRS at time of interview	
1-4	4 (22.2%)
5-10	4 (22.2%)
11-20	5 (27.8%)
21-50	5 (27.8%)

Table 3: AHCP Experience

Experience	N=6 (%)
Roles	
HCP Assistant	1 (16.7%)
Nurse	1 (16.7%)
Medical Assistant	3 (50.0%)
Clinical Research Coordinator	1 (16.7%)
Percentage of time spent providing direct care to patients	
100%	1 (16.7%)
80-99%	2 (33.3%)
50-79%	0 (0.0%)
20-49%	2 (33.3%)
<20%	1 (16.7%)

Preparation, Insertion, and Removal

- HCPs and AHCPs considered Gem-iDRS insertions and removals to be quick and "straightforward", with majority <5 minutes and could be performed in various non-surgical settings.
- HCPs indicated ~5-10% of their cases were complex, mostly among men and often due to prostatic enlargement, urethral stricture, or prolapsed anatomy in women, adding 1-2 minutes.
- Removals and subsequent insertions were often performed during the same visit.
- AHCPs reported that preparation and cleanup took no longer than 30 minutes in total.
- Gem-iDRS was found to be generally easy to store and manage in practice.

Adverse Event Management

- Lidocaine jelly was often utilized before procedures for comfort.
- Video instructions were described as the most utilized manufacturer materials.
- AHCPs reported patient education took approximately 30 minutes in total and described the process as explaining the Gem-iDRS system and procedure, using manufacturers' educational materials as needed, and discussing side effects and mitigation strategies.
- HCPs considered Gem-iDRS to be better tolerated, with local and mild AEs, and less time-consuming than other intravesical treatments, including BCG and chemotherapy.

Care Evolution

- Over half of the HCPs reported anticipating insertion and removal could be transitioned to advanced practice providers (APPs; e.g., nurse practitioners or physician assistants) in RW settings.
- AHCPs reported an interest in having APPs trained to perform insertions/removals once Gem-iDRS is commercially available.

Table 4: Select HCP Participant Quotations for Key Domains

Domain	HCP Quotations
Insertion	"It's **very quick.** It takes maybe 30 seconds to get the catheter in and then another minute to put the lube,system, lube, push, get out. It's really not hard at all." (Participant 1, Community practice)
Removal	"The [removal] process takes **less than one minute**. It's just scope in, grab the device, scope out." (Participant 3, Community practice)
Urologist and Patient-Friendly Procedure	"The mechanism…that slow **releases chemotherapy in the bladder 24/7**, instead of for one-to-two hours per week like conventional intravesical chemotherapy, that **really appeals** [to patients and HCPs]." (Participant 2, Community practice) "I think that the whole platform is so **easy to use** and **patient-friendly** that it's going to be interesting to me to see how long it takes for it to move further upstream to where perhaps even people who have never seen BCG can be placed directly on pretzel* at their initial diagnosis. I think that it's so friendly that our practices would rather do that." (Participant 3, Community practice)
Straightforward vs. Complex Cases	"I would say **95%** of cases have been **straightforward**. The 5% percent that've been complex are typically patients with a very large prostate and a high-riding bladder neck." (Participant 4, Community practice)
Adverse Events	"There's **nothing we're really actively monitoring for**. It's almost all related to frequency, urgency, and voiding symptoms. Most of those are **manageable**." (Participant 6, Community practice)
Comparison with Intravesical Treatments	"In the trial setting, it was highly successful, **much more successful than the other agents** that we currently have. It's **well tolerated** by the patients and its **less time-intensive than** doing gemcitabine or docetaxel." (Participant 7, Community practice) "Oh, it's great. It's an advantage [to not have patients travel so often]. I think it's going to pull patients towards [Gem-iDRS] that are coming from distances. Every three weeks versus once a week for six weeks is a big difference for them." (Participant 8, Academic practice)
Care Evolution	"It is so **easy to imagine some of the APPs** learning how to do it, just because it's an **easy thing**. They're in-clinic more often than I am, like two days a week, but I'm operating three days a week. If I go to a meeting or vacation, I don't want to interrupt people's treatment." (Participant 9, Academic practice)
Addressing Unmet Needs	"These people are **very desperate for an option to keep their bladder.** They don't want a cystectomy. They are really motivated." (Participant 5, Community practice)
Recommending Gem-iDRS	"The most important aspect is the **cancer efficacy**. The data so far suggests that it's **superior to the other approved treatments**. I don't see a reason for them not to be informed and strongly consider it in discussion with patients who want to preserve their bladder." (Participant 9, Academic practice) "I think this would be **easy for most practices to implement**. This would be something that I would recommend for them probably over some of these other intravesical agents just because some of the workflow issues, storage issues, and nursing requirements [of other intravesical agents] may be a little more challenging for some of these smaller practices." (Participant 8, Academic practice)

*Full FDA approved indication is BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors

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