# A Conceptual Model for Advanced/Metastatic Gastric or Gastroesophageal Junction Cancer: Results from a Targeted Literature Review and Patient Interviews

**PCR251** 



France Ginchereau Sowell, 1\* Thom de Milliano, 2 Keri JS Brady, 3 Ginamarie Foglia, 4 Medha Sasane, 3 Samira Bensfia 3 and Matthew Reaney 5

<sup>1</sup>Patient Centered Solutions, IQVIA, New York, NY, USA; <sup>2</sup>Consulting Services, IQVIA, Amsterdam, Netherlands; <sup>a</sup> Sanofi, Bridgewater, NJ, USA; <sup>a</sup> Fatient Centered Solutions, IQVIA, Reading, UK <sup>a</sup>Affiliations at the time of the study. Current affiliations for the relevant authors are: TdM, Santen Pharmaceutical, Amsterdam, Netherlands; GF, Shabas Solutions LLC, VA, USA. \*Correspondence: france.ginchereau@iqvia.com

## Background and objectives

- Despite recent approval of first-line immunotherapy treatments, patients with advanced/metastatic gastric cancer/gastroesophageal junction cancer (aGC/GEJC) have a median survival of ~14 months.1
- This study aimed to understand the health-related quality of life of patients living with aGC/GEJC and to:
- explore the symptoms experienced by patients caused by aGC/GEJC, related treatment, and/or surgery understand the impact of aGC/GEJC on patients' lives.

### Methods

- A targeted literature review (TLR) was conducted to identify qualitative research in aGC/GEJC from 2018 to 2021. This was reviewed alongside a patient interview study<sup>2</sup> and a review of health-related quality of life studies and patient blogs, both published in 2017.3
- Using the published patient experience data, an interview guide was developed for use in one-to-one semi-structured concept elicitation (CE) telephone interviews with patients.
- Interview data were coded using Atlas.ti following a framework.
- A conceptual model was developed based on the CE interview findings and the TLR.

#### Results

- The TLR identified four qualitative studies from 2018 and 2021. When reviewed alongside data from the two prior publications,<sup>2,3</sup> 47 symptoms and 35 impacts of aGC/GEJC were identified.
- Twenty patients were interviewed (baseline characteristics are reported in **Supplementary Table 1**).
- Most patients (65%) were women and nearly all patients (95%) were White.
- Most patients (60%) had previously undergone surgery.
- Four sets of five interviews identified 36 symptoms and 31 impacts. No new symptoms/impacts emerged in the final set of interviews, meaning that concept saturation was reached.
- The most common impacts were 'requiring assistance from caregivers', 'impacts on family and daily activities', and 'emotional disturbances'.
- The 12 most important symptoms (mentioned by ≥ 50% of patients; average disturbance ratings: ≥ 5, scale: 0, not disturbing at all, to 10, extremely disturbing) were: nausea, fatigue, sensitivity to temperature, indigestion, weakness, diarrhea, vomiting, early satiety, difficulty in swallowing, taste alteration, abdominal pain, and other pain.
- Figure 1 shows the conceptual disease model and patient interview quotations.

#### Limitations

- The literature review included only qualitative literature from June 2017 to January 2021.
- The patients interviewed were well educated (75% with a higher level of education than high school) and were not diverse: all 20 participants were from the USA and 19 were White.

# Figure 1. Conceptual disease model and patient interview quotations

Nausea 66 I had significant nausea and vomiting from the very first cycle. I felt bad anyway, and then the chemo made me feel worse

Fatigue 66 At its worse, I just don't get out of bed for 30 plus hours

disturbances

Emotional 66 The disease forces you to confront your mortality in a number of ways

Signs and symptoms

**V** + #

**V** + #

**V** + #

**\*\*** + #

**V** + #

**V** + #

**V** + #

**\*** + #

+ # Mouth sores

Skin problems

**Excessive sweating** 

Hearing impairment

Breathing problems 
+

**Bloating** 

Headache

Swelling

Bleeding

Hiccups

Spasms

Itching

Cough

# Surgery-related concepts

Back pain

Bone pain

Sensitivity to odor

**Gum problems** 

Eye problems

Patient population

Patients with aGC/GEJC

Disease process

Gastric mucosal

cells cause uncontrolled

cell proliferation and spread

within the stomach to

proximal organs and

distal organs

**Treatments** 

Therapies

Chemotherapy

Targeted therapy

Immunotherapy

Disease-related concepts

Endoscopic resection

Radiofrequency ablation

of 0-10, with 0 = not disturbing at all and 10 = extremely disturbing.

aGC/GEJC, advanced/metastatic gastric cancer/gastroesophageal junction cancer.

<sup>a</sup>Reported by ≥ 50% of patients. <sup>b</sup>Reported by ≤ 50% of patients.

Radiotherapy

Gastrectomy

High frequency<sup>a</sup>

Nausea

**Fatigue** 

Weight loss

Neuropathy

Sensitivity to

temperature

Indigestion

Constipation

**Early satiety** 

**Taste alteration** 

**Abdominal pain** 

Loss of appetite

Treatment-related concepts

**Bold text** highlights symptoms that were most important to patients in the interviews, that is, those with a disturbance rating ≥ 5 on a scale

Flatulence

Difficulty in

swallowing

Vomiting

Weakness

Other pain

Diarrhea

Hair loss

Low frequency<sup>b</sup>

**/** + #

+ #

**V** +

**/** +

**/** +

Activities of daily living

- Reduction in recreational activities
- Work productivity
- Stopped working

Role functioning

Social impacts

Family impact

 Unable to take care of family members

Financial impacts

Financial difficulties

Self-efficacy

Inability to drive

Requiring assistance

Cognitive impacts

Dizziness

Confusion

- Cognitive problems
- Speech difficulties
- Unable to read

Impacts

- Emotional impacts Worry
  - Stress
  - Fear
  - Change in appearance
  - Mood alterations
  - Feeling disappointed
  - Panic attacks
  - Feeling guilty
  - Hesitation to take treatment

Physical impacts

Walking difficulties

Quality-of-life impacts

- Eating habits
- Changes in lifestyle
- Change in diet
- Sleep disturbance

COVID-19-related impacts

COVID-19-related impact

Indigestion 6

I have bile reflux because I don't have a stomach, so what the gastroenterologist told me is happening is that the bile backs up into my esophagus

temperature

Sensitivity to 66 The cold sensitivity, when it was happening, was the worst

# Conclusions

- The conceptual disease model provides valuable data on the most important symptoms and impacts of aGC/GEJC that affect patients' lives, their experiences of care, and their willingness to participate in clinical trials.
- These results should be considered when defining the efficacy of innovative treatments, including the choice of patient-reported outcome strategy, to ensure that these treatments are well tolerated and improve both patient survival and health-related quality of life.

#### **Acknowledgments**

 Medical writing support was provided by Barbara Xella and Helen Fishpool of Oxford PharmaGenesis, Oxford, UK and was funded by Sanofi. Jennifer Fine at Sanofi, Paris, France, assisted with organizing this study. This study was sponsored by Sanofi.

#### **Disclosures**

MS and SB are employees of Sanofi and may hold shares and/or stocks in the company. GF and KJSB were employees of Sanofi at the time of this study. FGS and MR are employees of IQVIA and may hold shares and/or stocks in the company. TdM was an employee at IQVIA at the time of this study.

- 1. Janjigian YY et al. J Clin Oncol 2024:Jco2301601.
- 2. Martin S et al. Abstract presented at the 19th ESMO World Congress on Gastrointestinal Cancer, 28 June-1 July 2017, Barcelona, Spain.
- 3. Morlock R et al. Abstract presented at the 20th Annual European Congress of the International Society for Pharmacoeconomic and Outcomes Research, 4–8 November 2017, Glasgow, UK.