Online supplement

The healthcare professionals’ perspective on impact and actions taken following severe infusion reaction events in oncology centers in Europe

Journal: Drugs – Real World Outcomes

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Your characteristics
In order to better understand your work environment we would like you to fill in the following information:

1. In which type of hospital are you working in?
   - University hospital/ Teaching Hospital
   - Cancer Centre
   - Public general hospital
   - Private hospital/ clinic
   - Other please specify

2. What is your current position in your hospital?
   - Head Nurse
   - Oncologist
   - Safety Manager/pharmacist
   - Other please specify

3. For how long have you been in this position?
   - Less than a year
   - 1- 2 years
   - 3-5 years
   - More than 5 years

4. How many beds are available for the patients in the structure you work in?
   - Less than 100 beds
   - 100-199 beds
   - 200-499 beds
   - More than 500 beds

4bis. If there is an Oncology Unit in the setting you work in, how many beds are in this unit?

5. On average, how many cancer patients are managed in your day hospital?

6. Please select and rank the five main cancer indications managed in your day-hospital. For each cancer indication selected, please also give the approximate proportion of the cancer indications managed in your day hospital it represents.

| Cancer Indication | Rank | % of Total Cancer Indications |
|-------------------|------|------------------------------|
| Lung cancers      |      |                              |
| Breast cancers    |      |                              |
| Other gynecological cancers (ovarian, endometrial, etc.) | | |
| Prostate cancers  |      |                              |
| Testicular cancers|      |                              |
| Kidney cancers    |      |                              |
| Pancreatic cancers|      |                              |
| Gastric cancers   |      |                              |
| Colorectal cancers|      |                              |
| Head and neck cancers |     |                              |
| Multiple myeloma  |      |                              |
| Lymphoma          |      |                              |
| Other please specify |     |                              |

7. How many infusion chairs are available in your day hospital?

8. On average, how many cancer patients are receiving their infusion per day?

9. What is the composition of the medical dedicated team in your day oncology unit?
   Please tick the different members, specify if their presence is permanent or occasional and write their number.

| HCPs                                | Permanent | Occasional | How Many in Total |
|-------------------------------------|-----------|------------|------------------|
| Oncologist(s)/Hematologist(s)       |           |            |                  |
| Allergist(s)/Immunologist(s)        |           |            |                  |
| Oncology                            |           |            |                  |
| Head Nurse(s)                       |           |            |                  |
| Oncology Nurse(s)                   |           |            |                  |
| Nursing auxiliary (ies)              |           |            |                  |
| Social Worker(s)                    |           |            |                  |
| Other (please specify:              |           |            |                  |
**Pre infusion time**

*Here are some possible steps that can be in place to prevent and manage severe infusion reaction. Please check all the actual steps, process, actions and tick all that apply. This will be discussed during the further interview.*

| ACTION CONSIDERED IN THE RISK ASSESSMENT | PREMEDICATION CONSIDERED TO PREVENT INFUSION REACTION |
|------------------------------------------|---------------------------------------------------------|
| **Patient characteristics (age, sex status, comorbidities, history)** | **Corticosteroids to prevent infusion reaction** |
| □ Systematically considered | □ Systematically considered |
| □ Frequently considered | □ Frequently considered |
| □ Occasionally considered | □ Only considered for high risk patients |
| □ Only considered for some agents/classes (please tick all that apply): | □ Only considered for some agents/classes (please tick all that apply): |
| □ Monoclonal antibodies | □ Monoclonal antibodies |
| □ Platinum salts | □ Platinum salts |
| □ Taxanes | □ Taxanes |
| □ Other chemotherapy (specify):__________ | □ Other chemotherapy (specify):__________ |
| □ Rarely considered | □ Rarely considered |
| □ Never considered | □ Never considered |

| **Specific history of infusion reaction** | **Antihistamines to prevent infusion reaction** |
|------------------------------------------|-----------------------------------------------|
| □ Systematically considered | □ Systematically considered |
| □ Frequently considered | □ Frequently considered |
| □ Occasionally considered | □ Only considered for high risk patients |
| □ Only considered for some agents/classes (please tick all that apply): | □ Only considered for some agents/classes (please tick all that apply): |
| □ Monoclonal antibodies | □ Monoclonal antibodies |
| □ Platinum salts | □ Platinum salts |
| □ Taxanes | □ Taxanes |
| □ Other chemotherapy (specify):__________ | □ Other chemotherapy (specify):__________ |
| □ Rarely considered | □ Rarely considered |
| □ Never considered | □ Never considered |

| **Specific history of allergy** | **Other premedication:** |
|--------------------------------|-------------------------|
| □ Systematically considered | |
| □ Frequently considered | |
| □ Occasionally considered | |
| □ Only considered for some agents/classes (please tick all that apply): | |
| □ Monoclonal antibodies | |
| □ Platinum salts | |
| □ Taxanes | |
| □ Other chemotherapy (specify):__________ | |
| □ Rarely considered | |
| □ Never considered | |

| **According to the administration position in the cycle (1st one, 2nd one, 8th one, etc.)** | **In which cases?** |
|------------------------------------------|---------------------|
| □ Systematically considered | |
| □ Frequently considered | |
| □ Occasionally considered | |
| □ Only considered for some agents/classes (please tick all that apply): | |
| □ Monoclonal antibodies | |
| □ Platinum salts | |
| □ Taxanes | |
| □ Other chemotherapy (specify):__________ | |
| □ Rarely considered | |
| □ Never considered | |

| **Other risk assessment:** | **In which cases?** |
|--------------------------------|---------------------|
| | |
### Infusion time

#### MONITORING...

| During all the administration time for all administration cycle |
|---------------------------------------------------------------|
| - Systematically considered                                  |
| - Frequently considered                                      |
| - Only considered for high risk patients                     |
| - Only considered for some agents/classes (please tick all that apply): |
|   - Monoclonal antibodies □ Platinum salts □ Taxanes □ Other chemotherapy (specify):__________ |
| - Rarely considered                                           |
| - Never considered                                            |

| During all the administration time for selected administration cycle only |
|---------------------------------------------------------------------------|
| - Systematically considered                                               |
| - Frequently considered                                                   |
| - Only considered for high risk patients                                  |
| - Only considered for some agents/classes (please tick all that apply): |
|   - Monoclonal antibodies □ Platinum salts □ Taxanes □ Other chemotherapy (specify):__________ |
| - Rarely considered                                                       |
| - Never considered                                                        |

| During the 1st hour of administration of all cycles                      |
|--------------------------------------------------------------------------|
| - Systematically considered                                               |
| - Frequently considered                                                   |
| - Only considered for high risk patients                                  |
| - Only considered for some agents/classes (please tick all that apply): |
|   - Monoclonal antibodies □ Platinum salts □ Taxanes □ Other chemotherapy (specify):__________ |
| - Rarely considered                                                       |
| - Never considered                                                        |

| During the 1st hour of administration for specific cycles only           |
|--------------------------------------------------------------------------|
| - Systematically considered                                               |
| - Frequently considered                                                   |
| - Only considered for high risk patients                                  |
| - Only considered for some agents/classes (please tick all that apply): |
|   - Monoclonal antibodies □ Platinum salts □ Taxanes □ Other chemotherapy (specify):__________ |
| - Rarely considered                                                       |
| - Never considered                                                        |

- No monitoring required
#40JB68

SEVERE & SERIOUS INFUSION REACTIONS

45 min in-depth telephone interview

RECRUITMENT QUESTIONNAIRE HCPs

COUNTRY: __________________

PLEASE PRINT

| Name:          |                                                                 |
|---------------|-----------------------------------------------------------------|
| Address:      |                                                                 |
|               |                                                                 |
|               |                                                                 |
| Telephone number: |                                                       |
| Cell phone number: |                                                      |
| Date and time of interview: |                                                |
| Location of interview: |                                                  |
| Name of interviewer: |                                                  |
STUDY DESIGN

The overall aim of the study is to assess the impact of serious and severe infusion-related reactions across cancer indications in terms of prevention, safety procedures and internal center regulations.

Telephone-depth interviews (TDIs) of 45 minute each.

- **TWO** targets are to be recruited by hospital center among the 3 study targets.
- No strict quotas for each target, however a minimum of 4 (2 in the UK) safety managers/ hospital pharmacists each is required

|                    | France | Germany | UK  | Spain |
|--------------------|--------|---------|-----|-------|
| Head Nurses        | 20     | 20      | 14  | 20    |
| Oncologists        |        |         |     |       |
| Safety manager / hospital pharmacists | 20 | 20 | 14 | 20 |

RECRUITMENT PROCESS

- 10 centers will be sampled from each of the following countries: Germany, France, Spain and Italy
- 7 centers will be recruited from the UK.
- Of the 3 stakeholders identified from each center 2 will be selected for interview based on availability and willingness to participate giving a total of **20 (14 in the UK)** interviews.

INCLUSION CRITERIA FOR THE HOSPITAL CENTER:

- Must treat at least 20 cancer patients per day in day-hospital
- At least 1 severe/serious infusion reaction (grade 3-5) in the past 5 years

Introduction

Good morning / afternoon / evening, my name is <SAY YOUR OWN NAME>, and I am calling from Kantar Health. Kantar Health is a company specialized in Healthcare Research that has been commissioned by Amgen Limited to conduct an international survey on infusion related reactions across cancer indications in day-hospitals, and more specifically severe infusion reactions, from grade 3 to 5. The objective of this survey is to understand the process in place in day-hospitals in Europe to manage these kinds of adverse events.

I was wondering if you would be willing to take part in our research. The survey consists in a phone interview of 45 minutes scheduled at your convenience to discuss this topic.

You will receive <INSERT THE AMOUNT> €, as compensation for your time spent on this study.

The interview is carried out in accordance with the Data Protection Laws and within the strict respect of confidentiality guidelines. The interview will be audio-recorded for analysis purposes only. Your responses will be collated with other respondents’ and presented to Amgen Limited in an aggregated anonymous form. Only Kantar Health will be able to link your identity and your responses to you during the time of the study. Amgen Limited will not be able to link your identity to your responses.

However, Amgen Limited is committed to compliance with applicable laws and the EFPIA Code and the Local Country Implementation Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations. For that, it will be asked you to sign a Letter Agreement in which the study description, your compensation, your Personal Information like your name, surname and your professional address will be mentioned.
As part of this Letter Agreement, it will be asked you if you agree or not that Amgen Limited publicly discloses your personal information for Transfers of Value reporting (individual financial disclosure). You will have the right to refuse the individual financial disclosure. In that case, the transfer of value will be disclosed on an aggregate basis without any reference to your person and you can continue to participate to the study.

This Letter Agreement including your Personal Information and your individual financial disclosure consent will be shared with Amgen Limited. If you refuse to sign the Letter Agreement and have your Personal Information shared with Amgen Limited, you will not be able to participate in this survey.

In line with this, we require your specific agreement with the above information:

| 1 | I agree with the above information stated | ➔ CONTINUE WITH THE SCREENING QUESTIONS |
| 2 | I do not agree with the above information stated | ➔ THANK & CLOSE |

**Moderator/recruiter:** If the respondent agrees with all the above information, please ask **them** to sign below at the time of the interview.

*Respondent Name* ______________________________

*Date:* ________________________________________________

*Respondent signature* ________________________________

May I ask you a few questions to ascertain whether this survey is relevant to you? *CONTINUE IF RESPONDENT AGREES OR SUGGEST CALLING BACK AT A MORE CONVENIENT TIME IF RESPONDENT IS BUSY.*
ALL

1. What is your role?

| Role                                                                 | GO TO |
|----------------------------------------------------------------------|-------|
| Oncologist                                                           | Q2    |
| Oncology Head Nurse                                                  | Q2    |
| Safety/ Pharmacovigilance manager/ Risk manager / Quality Manager / Medical Information manager | Q2    |
| Hospital Pharmacist                                                  | Q2    |
| Other                                                                | THANK & CLOSE |

2. In what type of setting are you currently working?

| Setting                                                                 | GO TO |
|------------------------------------------------------------------------|-------|
| University hospital/ Teaching Hospital                                  | Q3    |
| Cancer Centre                                                          |       |
| Public general hospital                                                |       |
| Private hospital/ clinic                                               |       |
| GER ONLY : Private practice                                           | Q3    |

3. IF CODE 1-4 ASK: How many beds are available for the patients in the setting you work in?

| Beds available             | GO TO |
|----------------------------|-------|
| Less than 100 beds         | Q4    |
| 100-199 beds               |       |
| 200-499 beds               |       |
| More than 500 beds         |       |

4. ONLY IF ONCOLOGIST WORKING IN PRIVATE PRACTICE: CODE 1 in Q1 + CODE5 IN Q2: Do you work with a nurse in your office/clinic?

| Work with nurse? | GO TO |
|------------------|-------|
| Yes              | Q5    |
| No               | THANK & CLOSE |

5. How many treatment chairs are available in your oncology day-hospital unit / clinic?

IF LESS THAN 3 ➔ CLOSE
IF MORE THAN 3:
_____________ treatment chairs

6. Approximately how many cancer patients are treated in your day-hospital per day – all cancer types?

_____________ cancer patients/day

IF LESS THAN 20 ➔ CLOSE
IF MORE THAN 20
➔ IF ONCOLOGIST (CODE 1 IN Q1)➔ Q7
➔ IF NURSE (CODE 2 IN Q1)➔ Q15
➔ IF SAFETY MANAGER (CODE 3 OR 4 IN Q1)➔ Q22
ONCOLOGISTS

7. For how many years have you been practicing as an oncologist?
   ____________ years of experience as an oncologist
   IF LESS THAN 5 AND MORE THAN 30 YEARS → CLOSE
   IF NOT → GO TO Q8

8. Are you responsible for the day-hospital oncology unit or are you in charge of/ supervising the cancer out-patients receiving their treatment in the day-hospital unit?

|   |   |
|---|---|
| 1 | Yes | → GO TO Q9 |
| 2 | No  | → THANK & CLOSE |

9. For how long have you been working in your current setting?
   ____________ years of work in this setting
   IF LESS THAN 5 YEARS → CLOSE
   IF MORE THAN 5 YEARS → GO TO Q10

10. How many out-patients do you see per week in the day-hospital?
    ____________ patients/week

11. What proportion of your time is dedicated to direct patient care (treating patients), as opposed to other activities (such as teaching/lecturing, research, administrative tasks...)?
    _______ % of time dedicated to direct patient care
    IF LESS THAN 50% → CLOSE
    IF MORE THAN 50% → GO TO Q12

12. Have you witnessed or are you aware of a severe/serious case of infusion reaction occurring in your current day-hospital oncology setting during the last 5 years? By severe we mean a grade 3-5 event as described here by the National Cancer Institute:

| Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---------|---------|---------|---------|---------|
| Transient flushing or rash | Rash; flushing; urticaria; dyspnea; drug fever ≥38°C | Symptomatic bronchospasm, with or without urticaria; allergy-related edema / angioedema; hypotension | Anaphylaxis | Death |

|   |   |
|---|---|
| 1 | Yes, I directly witnessed such an event | → GO TO Q14 |
| 2 | Yes, I did not directly witnessed the event but indirectly know about it and about its consequences | → GO TO Q14 |
| 3 | Yes, but I do not know anything about this event | → GO TO Q13 |
| 4 | I do not know | → THANK & CLOSE |
| 5 | No | → THANK & CLOSE |

13. IF CODE 3 IN Q12: Do you know who another HCP in your setting that could tell us about this event and that we should contact? PLEASE NOTE THE CONTACT

   _______________________________________________________________________

14. Could you please tell me your age? ____________ years old

   DO NOT ASK AND PLEASE NOTE/

|   |   |
|---|---|
| 1 | Man | → GO TO Q29 |
| 2 | Woman | → THANK & CLOSE |
HEAD NURSE

15. For how many years have you been practicing as a head nurse?

_____________ years of experience as a head nurse

IF LESS THAN 5 AND MORE THAN 30 YEARS ➔ CLOSE
IF NOT ➔ GO TO Q16

16. Are you responsible for...
READ AND TICK ALL THAT APPLY

| Code | Description                                                                 | Yes | No |
|------|-----------------------------------------------------------------------------|-----|----|
| 1    | supervising the team of nurses working in the oncology day-hospital?        | ☐   | ☐  |
| 2    | managing cancer patients receiving IV treatment in the day-hospital?        | ☐   | ☐  |
| 3    | Educating patients about the treatment administration?                     | ☐   | ☐  |

IF ‘YES’ TO CODES 1 TO 3 ➔ GO TO Q17
IF ‘NO’ TO ONE OF THE CODE ➔ THANK & CLOSE

17. For how long have you been working in your current setting?

_____________ years of work in this setting

IF LESS THAN 5 YEARS ➔ CLOSE
IF MORE THAN 5 YEARS ➔ GO TO Q18

18. What proportion of your time is dedicated to direct patient care (in contact with patients), as opposed to other activities (such as team management, administrative tasks...)?

_______ % of time dedicated to direct patient care

IF LESS THAN 50% ➔ CLOSE
IF MORE THAN 50% ➔ GO TO Q19

19. Have you witnessed or are you aware of a severe/serious case of infusion reaction occurring in your current day-hospital oncology setting during the last 5 years? By severe we mean a grade 3-5 event as described here by the National Cancer Institute:

| Grade 1 | Grade 2                                                                 | Grade 3                                                                 | Grade 4       | Grade 5       |
|---------|--------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------|---------------|
| Transient flushing or rash | Rash; flushing; urticaria; dyspnea; drug fever ≥38°C | Symptomatic bronchospasm, with or without urticaria; allergy-related edema / angioedema; hypotension | Anaphylaxis | Death |

1 Yes, I directly witnessed such an event ➔ GO TO Q21
2 Yes, I did not directly witness the event but indirectly know about it and about its consequences ➔ GO TO Q21
3 Yes, but I do not know anything about this event ➔ GO TO Q20
4 I do not know ➔ THANK & CLOSE
5 No ➔ THANK & CLOSE

20. IF CODE 3 IN Q19: Do you know who another HCP in your setting that could tell us about this event and that we should contact? PLEASE NOTE THE CONTACT

________________________________________________________________________

21. Could you please tell me your age? ____________ years old

DO NOT ASK AND PLEASE NOTE:

| Code | Description |
|------|-------------|
| 1    | Man         |
| 2    | Woman       ➔ GO TO Q29 |
SAFETY MANAGER

22. What is your title? PLEASE NOTE THE EXACT TITLE

____________________________________________________________________

23. For how many years have you been practicing as a [TITLE MENTIONED IN Q22]? 

______________ years of experience as a safety manager

IF LESS THAN 5 AND MORE THAN 30 YEARS ➔ CLOSE
IF NOT ➔ GO TO Q24

24. Are you involved in or responsible for the following tasks (among others)?

READ AND TICK ALL THAT APPLY

| Code | Task Description | Yes | No |
|------|------------------|-----|----|
| 1    | Establishing internal policies and procedures regarding patients safety | ☐   | ☐  |
| 2    | Compliance with regulations and statutes issued by governing bodies | ☐   | ☐  |
| 3    | Management of emergency incident | ☐   | ☐  |
| 4    | Sensitizing and educating employees concerning safety process | ☐   | ☐  |

IF ‘YES’ TO CODES 1 TO 4 ➔ GO TO Q25
IF ‘NO’ TO ONE OF THE CODE ➔ THANK & CLOSE

25. For how long have you been working in your current setting?

______________ years of work in this setting

IF LESS THAN 5 YEARS ➔ CLOSE
IF MORE THAN 5 YEARS ➔ GO TO Q26

26. Have you witnessed or are you aware of a severe/serious case of infusion reaction occurring in your current day-hospital oncology setting during the last 5 years? By severe we mean a grade 3-5 event as described here by the National Cancer Institute:

| Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---------|---------|---------|---------|---------|
| Transient flushing or rash | Rash; flushing; urticaria; dyspnea; drug fever ≥38°C | Symptomatic bronchospasm, with or without urticaria; allergy-related edema / angioedema; hypotension | Anaphylaxis | Death |

1 Yes, I directly witnessed such an event ➔ GO TO Q28
2 Yes, I did not directly witness the event but indirectly know about it and about its consequences ➔ GO TO Q28
3 Yes, but I do not know anything about this event ➔ GO TO Q27
4 I do not know ➔ THANK & CLOSE
5 No ➔ THANK & CLOSE

27. IF CODE 3 IN Q26: Do you know who another HCP in your setting that could tell us about this event and that we should contact? PLEASE NOTE THE CONTACT

____________________________________________________________________

28. Could you please tell me your age? ________________ years old

DO NOT ASK AND PLEASE NOTE:

| Code | Code |
|------|------|
| 1    | Man  | ➔ GO TO Q29 |
| 2    | Woman| ➔ GO TO Q29 |
TO ALL

Recruitment
Thank you for answering these questions.
We would like to invite you to a 45 minutes phone interview to discuss the process in place to prevent and manage the severe infusion reaction in your oncology day-hospital, and talk about the latest event that occurred. Prior to the discussion, we would like you to complete a document focused on typical infusion administration in your center.

29. Are you willing to participate?

|   | YES | SCHEDULE DATE AND TIME FOR THE INTERVIEW | REPORT THE DETAILS ON THE FIRST PAGE |
|---|-----|----------------------------------------|-------------------------------------|
| 1 | NO  | THANK &CLOSE                            |

IF IT IS THE FIRST RESPONDENT OF THE STRUCTURE
As I explained at the beginning of the call, for this survey we also want to interview another person in your structure to have different HCPs perspectives. Do you know if <A safety manager/an oncologist/a head nurse MODERATOR TO ADAPT> will be interested by this study?
Please be aware that the content of the discussion we will have will not be shared with this person, as with anybody else without your consent.

|   | YES |  |
|---|-----|---|
| 1 | NO  |  |
#40JB68

SEVERE OR SERIOUS INFUSION REACTIONS

45 min in-depth telephone interview

Draft discussion guide – HCPs

SUMMARY OF THE KEY OBJECTIVES
(for the moderator / not to be read to the respondent)

• Understand the current regulations and possible procedures in place to prevent infusion related reactions in hospital oncology units that have experienced infusion reaction
  o Guidelines for management of adverse transfusion reactions (International/National/Local levels)
  o Identify, if any, the individuals/person in charge of the procedures
  o Determine the level of flexibility, adaptability of the procedures

• To gain specific knowledge of the stakeholders involved in the management of serious infusion reactions
  o Identify each role in the management of severe or serious infusion reactions
  o Describe the stakeholder interactions they have between them.
  o Determine stakeholders’ level of awareness of the risks
  o Establish stakeholders’ habits and experiences of such events

• Determine the impact of grade 3-4 past events on the hospital internal specific management of the infusion related severe or serious reactions and on the overall safety procedures
  o Most frequent and prominent impacts
  o Level of satisfaction regarding overall safety procedures
  o Unmet needs at all the levels
  o Possible ways of improvement prevention and management of infusion reactions

TARGETS

All the interviewees are directly involved in the cancer therapy and infusion reactions management at different levels.

• Head nurses: responsible for the day hospital nursing staff in the oncology unit
• Oncologists: working in a day hospital management in the Oncology unit
• Pharmacovigilance Managers/Safety Managers at the hospital level/ hospital pharmacists, responsible of the day hospital safety and regulations follow-up
• Germany/France/UK/Spain/Italy

Thank you for participating to this study.
• Presentation of moderator, Kantar Health/ agency and rules:

1. Kantar Health is specialized in Healthcare Research, working on behalf of pharmaceutical companies and medical device manufacturers.
2. The interview is carried out in accordance with the Data Protection Laws and within the strict respect of confidentiality guidelines. In this context, your responses to the interview will be collated with other respondents’ and presented to the sponsor in an aggregated anonymous form. Your name will never be mentioned.
3. The interview will be audio-recorded to help us with our analysis. This recording will not be used for any commercial purpose.
4. The discussion will last about 45 minutes.
5. Any questions before starting?

• Introduce the topic of the interview:

– Today, we are going to discuss about infusion related reactions and more specifically grades 3 and 4.
– The objective is to understand how severe or serious reactions when they occur are managed in your center in terms of prevention, process and organization.
– There is no right or wrong answers, we ask you to reply as freely and sincerely as possible. Your answers will help us to have a better understanding of current process and how they can be improved.
I. Introduction – 5’

1) First of all, can you briefly introduce yourself?
   a) First name only
   b) What is your current position in your hospital?
   c) For how long have you been in this position?

2) Can you specify the type of setting you work in? Please discuss the Respondents Characteristics self-completion sheet completed prior to the interview. Briefly check the answers given by the respondent with him and ask for clarification if necessary.
   a) In which hospital/structure?
   b) Size
   c) Main cancer indications

3) Could you please describe your role in detail? Spontaneous then probe on:
   a) What are your day-to-day responsibilities?
      i) [Oncologists Only] What is your specialty and main practice setting? Any sub-specialty or specialization?
      ii) [Oncologists and nurses only] What proportion of your time is dedicated to direct patient care, as opposed to other activities such as teaching/lecturing…?
      iii) [Head Nurses only] Are you involved in the therapeutic patient education? IF YES: Please explain your role and how you are involved in the patient education.
      iv) [Pharmacists or Safety managers only] With whom do you interact/work the most within the hospital? How?

II. Current process in place for the management of infusion reaction – 15’

Moderator say: Now I would like to focus on infusion reactions that can occur to cancer patients during treatment and how infusion reactions are managed in your day hospital/centre. We will need to have the ‘Pathway’ self-completion sheet at hand to base our discussion on.

4) In your opinion, how much of a challenge are severe or serious infusion reactions in your day hospital?
   a) Why? Why not?
   b) Which aspects, if any, are the most challenging?
   c) How frequent would you say are severe or serious infusion reactions in cancer patients in your day hospital?
   d) Are there any warning signs that all staff are trained to acknowledge and/or report? Which ones?
5) What are the processes in place in your day hospital to prevent the occurrence of infusion reactions or to reduce their impact? Spontaneously first then probe:

6) Let’s focus on each step more in details. Please refer to the ‘Pathway’ self-completion sheet for each step. First, is there any patient education/awareness? Why/why not? IF YES:
   a) What is communicated to the patient? What is the aim of the communication?
   b) Who is responsible for educating/communicating in the infusion reaction to the patient?

7) Is there any risk assessment of infusion reaction for each patient?
   a) What does this risk assessment typically consist of? What are the criteria taken into account in this risk assessment?
      i) Age?
      ii) Sex?
      iii) Comorbidities? Which ones in particular? Indication?
      iv) Treatment to be administered?
      v) History? Of previous events? Of allergy? Else? Please explain
   b) Who is responsible for this risk assessment?
   c) How systematically is this risk assessment done?
   d) How formalized is this risk assessment? Is it based on a specific questionnaire?
   e) Considering this risk assessment, who are the patients considered at high risk to experience a severe infusion reaction? Please define this high risk category of patients.

8) Is there any use of pre-medication or prophylactic medication to prevent severe infusion reactions? Please refer to the ‘pathway’ self-completion sheet
   a) In which circumstances?
   b) What pre-medication for which situation?
   c) Who is responsible for prescribing this premedication?

9) In terms of monitoring, what is in place?
   a) How would you define monitoring? What does it typically consist of?
   b) How does it differ for the patients ‘at risk’ you described to me earlier?
   c) How systematic is this monitoring? When does it apply?
   d) Who is responsible for this monitoring?

10) In the event of a severe infusion reaction, what is the process in place in your day hospital or centre? Please describe the processes laid down.
   a) What is done first? Describe the order of events
   b) Who is involved in the intervention?
   c) How is the patient handled?
   d) What follow-up plan is put in place, if any?
   e) Is there any specific process followed for grade 3-4 infusion reaction? Please explain.

11) Are these processes mentioned above based on guidelines? National, local? Or hospital guidelines, or a mix? Please explain Please also complete sheet 1
a) Who is responsible for establishing these processes?

b) When were these processes put in place? Were they put in place:
   i) After a specific event? OR
   ii) It’s what was done before, as a routine, not as a consequence of any specific event?

12) In your hospital/structure, who is in charge of the staff education on these processes?

13) And who is responsible for ensuring compliance to these processes?
   a) How is staff compliance with the process in place to prevent and manage severe infusion reactions monitored?
   b) Are there any external persons involved in compliance monitoring? Who? Why, what is their role?

14) Overall, how satisfied are you with the process in place to manage severe infusion reactions in your day hospital/centre? Why? Moderator: Please refer to and complete moderator sheet 2:
   a) In your opinion, how could it be improved?

III. Recall of one grade 3-4 event – 25

Moderator, say: Now, I would like to come back to the most striking event of severe (grade 3 or 4) infusion reaction you witnessed/knew of in your day hospital]

15) Please can you describe this event to me? Probe if not mentioned on:

16) What were the first clinical manifestations or signs of a severe infusion reaction? [Moderator: Spontaneously first, then probe if necessary:]
   a) Rashes?
   b) Flush?
   c) Alterations in heart rate and blood pressure?
   d) Dyspnea? Bronchospasm?
   e) Urticaria, oedema?

17) Who witnessed first the signs, noticed that something was wrong?
18) What happened then?
   a) What was done first?
   b) Who was involved at that stage?
   c) And then? And then?...
   d) Who was involved at that stage?
   e) How did the patient react?

19) How serious was this event, what grade was it?

20) Once the event was over, what was done in terms of monitoring and follow-ups?
   a) Follow-up plan
   b) Who was responsible for these follow-ups?

21) What were the consequences on of the severe infusion reaction event on staff?
   a) Immediate emotional reaction?
   b) Long-term impact on staff organization?
   c) Consequences on the hospital/center process and management of infusion reaction risks? How?

22) Thinking back, in your opinion, how well was this severe infusion event managed? Why?
   a) Were the reactions to the event and actions taken to manage the event optimal? Why?
   b) Was the staff involved sufficiently prepared?
   c) Is there anything that could have been done differently or avoided for a better outcome? Please explain.

23) Did this severe infusion reaction affect or change treatment processes for infusion-administered treatment in your hospital?
   a) How, what changes were implemented?
   b) For which reasons?
   c) Who did initiate these changes? Who was responsible for deciding those changes should be implemented?
   d) After this event has your hospital been audited on safety processes regarding cancer day-hospital patient’s infusion reaction?
      i) **IF YES:** Who was in charge of this audit?
24) In your opinion, is it likely that these processes change in the future?
   a) Why?
   b) IF YES: How will these process change?
   c) How will the roles and responsibilities within the hospital evolve in the future?
   d) What processes, organization and education/training would you like to see set-up or done in the future to ensure infusion safety?
   e) What further recommendations to prevent another serious IRs would you propose?

25) Our discussion is now ending; do you have anything to add?

Thanks & close
MODERATOR SHEET 1

Q11 Is it the process based on guidelines? International, national; local guidelines or guidelines edited at the hospital level? **Tick the correct answer and write the name of the guidelines**

☐ International guidelines:

_____________________________________________________

☐ National guidelines:

_____________________________________________________

☐ Local /hospital guide line

☐ Not based on any specific guidelines
**MODERATOR SHEET 2**

Q14). How satisfied are you overall with the management of infusion reactions in patients receiving cancer treatment in your day hospital? Please answer on a 5-point scale where 1 means ‘not at all satisfied’ and 5 means ‘very satisfied’.

*Moderator, please circle the answer below.*

| How satisfied are you with measures to prevent infusion reactions in patients receiving cancer treatment in your day hospital? |
|---|---|---|---|---|---|
| Not at all satisfied | 1 | 2 | 3 | 4 | 5 | Very satisfied |

| How satisfied are you overall with the management of infusion reactions in patients receiving cancer treatment in your day hospital? |
|---|---|---|---|---|---|
| Not at all satisfied | 1 | 2 | 3 | 4 | 5 | Very satisfied |