

**CHEMOTHERAPY OR EXCLUSION
FOR CISPLATIN-INTOLERANT PATIENTS
WITH LOCALLY ADVANCED CERVICAL CANCER**
Prototype for a Patient Decision Aid

XXX
26 January 2023

Who developed this patient decision aid?

This decision aid was developed by people that manage cervical cancer patients, a cervical cancer survivor, and a caregiver:

1. XXX, MD, *radiation oncologist*,
2. XXX, MD, *radiation oncologist*,
3. XXX, MD, *gynecologic oncologist*,
4. XXX, RN, *oncology nurse*,
5. XXX, PhD, *clinical psychologist*,
6. XXX, *cervical cancer survivor*, and
7. XXX, *caregiver*.

This project is partly funded by the Philippine Council for Health Research and Development.

How was this patient decision aid developed?

The Decision Support Framework (1998) and the International Patient Decision Aid Standards Collaboration – Model Development Process (2013) guided the development process.

The information presented are based on the following documents:

1. National Comprehensive Cancer Network Guidelines (NCCN, 2022)
2. Society of Gynecologic Oncologists of the Philippines Guidelines (SGOP, 2018), and
3. XXX: a systematic review and meta-analysis (XXX).

The clinical trials on combined chemotherapy and radiotherapy for cervical cancers do not include patients with contraindications to cisplatin. We reviewed the outcomes for these patients from 2 small clinical trials and 18 observational studies on patients treated from 1990 onwards (XXX). Overall, the current information form low-quality evidence.

The patient decision aid will be updated every 3-5 years as new information is published.

Who reviewed this patient decision aid?

The content of this decision aid was reviewed by the following:

1. Local, internal reviewer: XXX, MD, *radiation oncologist*, XXX, Philippines
2. Local, external reviewer: XXX, MD, *gynecologic oncologist*, XXX, Philippines
3. International reviewer: XXX, MD, *radiation oncologist*, XXX, Australia

What is this patient decision aid for?

This material is for those **deciding whether to add cisplatin to radiotherapy for locally advanced cervical cancer** when there are concerns about tolerating cisplatin.

This material is not a survey. This material will help you **reflect and better understand your treatment options and your situation** so you can reach a good and realistic decision. This material **does not replace the medical recommendation of your attending doctor/s**.

How do I use this patient decision aid?

This material has five parts and could take at least 30 minutes to complete. You could go over it, or some parts of it, alone or with your family or important others.

Part 1 will help remind you of **your actual situation** and allow you to reflect on your current treatment decision.

Part 2 (Patient Information Summary) will help you **better understand your cancer, your treatment options, and compare their benefits, risks, procedures, and costs**.

Part 3 will help you review the **most important points about your treatment options** and reflect about your treatment decision after reading the material.

Part 4 (Personal Worksheet) will help you examine **your feelings about your health, treatment, and situation**.

Part 5 will guide you with **how to proceed with the decision-making**.

Part 1.

Tell us about yourself.

1. How old are you? _____
2. Which of the following best describes your **marital status**? (Check one.)
 - ___ Never married
 - ___ Married
 - ___ With partner
 - ___ Separated
 - ___ Widowed
3. Which of the following best describes your **family status**? (Check one.)
 - ___ Living alone
 - ___ Living with spouse/partner with no children
 - ___ Living with spouse/partner with children
 - ___ Living with children
 - ___ Living with caregiver
4. Which of the following best describes your **educational attainment**? (Check one.)
 - ___ Finished primary school
 - ___ Finished junior high school
 - ___ Finished senior high school
 - ___ Finished college
 - ___ Finished post-graduate degree
5. Which of the following best describes your **employment status**? (Check one.)
 - ___ Unemployed
 - ___ Self-employed
 - ___ Employed part-time
 - ___ Employed full-time
 - ___ Retired
6. How would you describe your **socio-economic status**? (Check one.)
 - ___ Upper class
 - ___ Upper middle class
 - ___ Middle class
 - ___ Lower-middle class
 - ___ Lower class
7. Based on your understanding, what is the **stage** of your disease? _____
8. Based on your understanding, why might you not tolerate the cisplatin well? (Check one or more.)
 - ___ Kidney problems
 - ___ Heart problems
 - ___ Block in the urinary passages
 - ___ Advanced age
 - ___ Poor overall health
 - ___ Other medical problems (please state):

 - ___ Personal choice

How do you feel about your treatment decision at the moment?

Please check the corresponding box of your choice.

| | Strongly Disagree | Disagree | Unsure | Agree | Strongly Agree |
|--|-------------------|----------|--------|-------|----------------|
| 1. I am willing to get chemotherapy. | | | | | |
| 2. I understand the available treatment options for me. | | | | | |
| 3. The benefits and side effects of the treatment options are clear to me. | | | | | |
| 4. I have enough support and advice from others to decide. | | | | | |

5. Which of the following best describes your **treatment decision at the moment**?

- I want to learn more about my treatment options.
- I understand my options and want to discuss them with others.
- I am decided but will need to evaluate my resources and plan.
- I am decided and am ready to get the treatment.

Part 2.

What is cervical cancer?

Cervical cancer occurs when abnormal cells multiply out of control in your cervix. The cancer cells form a malignant tumor, which could bleed or cause pain.

Without treatment, the cancer could affect nearby organs such as your vagina, urine passages, bladder, and rectum, or spread to the lymph nodes. When they do, the cancer is **locally advanced** and may cause problems removing toxins from the blood, urinating, or moving bowels.

The cancer could spread through the blood to other body parts, such as the lungs, liver, and bones. When they do, the cancer is **metastatic** and may cause difficulty breathing, abdominal pain, bone pains, or fractures.

What is the treatment?

For locally advanced cervical cancer, surgery is not advised. The primary treatment is external radiotherapy followed by brachytherapy (internal radiotherapy). External radiotherapy is combined with chemotherapy, particularly **cisplatin**, to boost its effectiveness, maximize the chances of controlling the tumor, and improve survival.

External radiotherapy requires several daily visits to the treatment center. It commonly causes mild diarrhea and painful or frequent urination in the middle of the treatment course. The daily schedule and side effects usually affect your daily function and social activities temporarily, but do not commonly cause general weakness or loss of independence.

Cisplatin is given once weekly sessions at the treatment center at the same day that a radiotherapy session is given. It may cause vomiting and kidney problems, leading to dehydration or poor oral intake. It could also increase the radiotherapy side effects. Medications and supportive care are usually given to prevent or relieve these problems.

What are your options?

Your doctor may hesitate to give you cisplatin because you have kidney or heart problems, advanced age, poor overall health, or other important medical conditions. Or you may hesitate to get cisplatin because you are worried about its side effects, or due to other personal reasons.

- Your doctors may recommend giving cisplatin with adjusted lower dosage.
- Your doctors may recommend using a different chemotherapy drug that they feel you might tolerate better.
- Your doctors may recommend not getting chemotherapy at all, and therefore radiotherapy alone.

Let us compare your options.

| | Standard Chemoradiation (Radiotherapy + Cisplatin) | Modified Chemoradiation (Radiotherapy + Other Drug) | Radiotherapy Alone |
|----------------------------------|--|--|--|
| What is usually involved? | | | |
| Radiotherapy | <ul style="list-style-type: none"> • Preparation includes a pelvis CT scan about a week before the radiotherapy sessions. • A total of 25 to 30 daily outpatient treatments will be given from Mondays to Fridays. • Each session will take 10-15 minutes. • No isolation is necessary after each session. | | |
| Chemotherapy | <ul style="list-style-type: none"> • Cisplatin is the standard. • Cisplatin is injected into your veins. • Each session is given as an outpatient and lasts about 6 hours. • You may be admitted in the hospital if your doctors feel it is necessary. • Each session will be given once weekly, starting the same week that you start your radiotherapy sessions. • You will need a total of 5-6 sessions. | <ul style="list-style-type: none"> • Carboplatin is the recommended substitute. • Carboplatin and most other drugs are injected into your veins. • Some drugs come in pills. • For injected drugs, each session is given as an outpatient and lasts about 6 hours. • You may be admitted in the hospital if your doctors feel it is necessary. • Each session will be given once weekly, starting the same week that you start your radiotherapy sessions. • For carboplatin, you will need a total of 5-6 sessions. | <ul style="list-style-type: none"> • No chemotherapy. |

| | Standard Chemoradiation (Radiotherapy + Cisplatin) | Modified Chemoradiation (Radiotherapy + Other Drug) | Radiotherapy Alone |
|--|--|--|--|
| What are the benefits and chances? Chances are estimates for every 100 patients. | | | |
| Disease control and survival | <ul style="list-style-type: none"> • At 3 months, about 83 show complete tumor response. • At 5 years, about 80 survive and are cancer-free. The chance ranges from 58-93. • Earlier disease stage and timely treatment are associated with better chances. | <ul style="list-style-type: none"> • At 3 months, about 79 show complete tumor response. • At 5 years, about 71 survive and are cancer-free. The chance ranges from 46-91. • With carboplatin, about 54 survive and are cancer-free. The chance ranges from 41-67. • Earlier disease stage and timely treatment are associated with better chances. | <ul style="list-style-type: none"> • At 3 months, about 85 show complete tumor response. • At 5 years, about 63 survive and are cancer-free. The chance ranges from 32-90. • Earlier disease stage and timely treatment are associated with better chances. |

| | Standard Chemoradiation (Radiotherapy + Cisplatin) | Modified Chemoradiation (Radiotherapy + Other Drug) | Radiotherapy Alone |
|--|---|--|---------------------------------------|
| What are the side effects and chances? Chances are estimates for every 100 patients. | | | |
| Chemotherapy side effects (<i>any severity</i>) | | <ul style="list-style-type: none"> • With carboplatin: | |
| <i>Vomiting</i> | • Highly common (76-100) | • Highly common (81-93%) | |
| <i>Kidney problems</i> | • Very common (28-36%) | • Uncommon (<10%) | |
| <i>Hearing problems</i> | • Very common (31%) | • Uncommon (<10%) | |
| <i>Decreased blood counts</i> | • Very common (25-30%) | • Highly common (26-97%) | |
| <i>Nerve problems</i> | • Uncommon (<10%) | • Common (6-15%) | |
| <i>Allergic reaction</i> | • Common (1-20%) | • Uncommon (2-9%) | |
| Radiotherapy side effects during treatment | • May be increased by cisplatin. | • May be increased by carboplatin or the other drugs. | • Usually mild and manageable. |
| <i>Severe diarrhea</i> | • Uncommon (less than 10). | • Uncommon (less than 10). | • Rare (less than 5). |
| <i>Severe vomiting</i> | • Common (less than 15). | • Uncommon (less than 10). | • Rare (less than 5). |
| <i>Very painful urination</i> | • Uncommon (less than 10). | • Rare (less than 5). | • Rare (less than 5). |
| <i>Severe kidney problems</i> | <ul style="list-style-type: none"> • Rare (less than 5). • No estimate for those with kidney problems before treatment. | <ul style="list-style-type: none"> • Rare (less than 5). • Among those with kidney problems before treatment, worsening is rare (less than 5). | • Rare (less than 5). |
| <i>Severe drop in white blood cells (risk for serious infection)</i> | • Rare (less than 5). | • Very common (less than 22) | • Rare (less than 5). |
| Radiotherapy late side effects (after treatment) | • Not usually increased. | • Not usually increased. | • Usually mild and manageable. |

| | Standard Chemoradiation (Radiotherapy + Cisplatin) | Modified Chemoradiation (Radiotherapy + Other Drug) | Radiotherapy Alone |
|---|---|--|----------------------------|
| <i>Severe rectal bleeding, or painful or abnormal bowel movements</i> | • Uncommon (less than 10). | • Uncommon (less than 10). | • Uncommon (less than 10). |
| <i>Severe painful, frequent, or abnormal urination</i> | • Rare (less than 5). | • Rare (less than 5). | • Rare (less than 5). |
| <i>Severe kidney problems</i> | • Rare (less than 5). | • Rare (less than 5). | • Rare (less than 5). |

| | Standard Chemoradiation (Radiotherapy + Cisplatin) | Modified Chemoradiation (Radiotherapy + Other Drug) | Radiotherapy Alone |
|---|--|--|--|
| What are the chances of completing the treatment? Chances are estimates for every 100 patients. | | | |
| Chemotherapy | <ul style="list-style-type: none"> • About 84 complete 5-6 of the 6 cycles. | <ul style="list-style-type: none"> • About 80 complete 5-6 of the 6 cycles. | <ul style="list-style-type: none"> • No chemotherapy. |
| <i>Elderly patients (aged 65 or up)</i> | <ul style="list-style-type: none"> • About 89 can complete. | <ul style="list-style-type: none"> • About 67 can complete. | |
| <i>Patients with kidney problems</i> | <ul style="list-style-type: none"> • No estimate. | <ul style="list-style-type: none"> • About 89 can complete. | |
| Radiotherapy | <ul style="list-style-type: none"> • About 97 can complete. | <ul style="list-style-type: none"> • About 89 can complete. • With carboplatin, 92 can complete. | <ul style="list-style-type: none"> • About 97 can complete. |

| | Standard Chemoradiation (Radiotherapy + Cisplatin) | Modified Chemoradiation (Radiotherapy + Other Drug) | Radiotherapy Alone |
|---|---|---|---|
| What are the additional costs of chemotherapy? | | | |
| Cost of chemotherapy drug | <ul style="list-style-type: none"> • Cisplatin is an inexpensive drug. | <ul style="list-style-type: none"> • Carboplatin is nearly twice as expensive as cisplatin. • Other drugs may be more expensive. | <ul style="list-style-type: none"> • No chemotherapy is given. |
| Transportation costs | <ul style="list-style-type: none"> • Usually no additional costs – the drug is given on the same day as the radiotherapy session is given. | <ul style="list-style-type: none"> • Usually no additional costs – the drug is given on the same day as the radiotherapy session is given. | |
| Treatment costs | <ul style="list-style-type: none"> • May be increased due to hospitalization or supportive care to prevent or manage toxicity. | <ul style="list-style-type: none"> • May be increased due to hospitalization or supportive care to prevent or manage toxicity. | |

Part 3.

What have you learned so far?

1. *What is the standard treatment for locally advanced cervical cancer? (Check one.)*
 Radiotherapy with cisplatin followed by brachytherapy.
 Radiotherapy followed by brachytherapy.
 I'm not sure.
2. *Is chemotherapy the main treatment for locally advanced cervical cancer? (Check one.)*
 Yes.
 No.
 I'm not sure.
3. *Are the side effects of chemotherapy always severe? (Check one.)*
 Yes.
 No.
 I'm not sure.
4. *Can the side effects of chemotherapy usually be managed or prevented? (Check one.)*
 Yes.
 No.
 I'm not sure.
5. *When there are concerns for cisplatin toxicity, what are the treatment options? (Check one or more.)*
 Adjust cisplatin dose.
 Substitute cisplatin with other drugs.
 Give radiotherapy without chemotherapy.
 I'm not sure.

Let's check the facts.

1. *What is the standard treatment for locally advanced cervical cancer?*
2. *Is chemotherapy the main treatment for locally advanced cervical cancer?*
3. *Are the side effects of chemotherapy always severe?*
4. *Can the side effects of chemotherapy usually be managed or prevented?*
5. *When there are concerns for cisplatin toxicity, what are the treatment options?*

The standard treatment is radiotherapy with cisplatin followed by brachytherapy. The chances for survival are best with this treatment.

No. The main treatment is radiotherapy. **Chemotherapy is given to boost the effectiveness of radiotherapy and to increase survival.**

No. **The chances for severe side effects range from rare to common.**

Yes. **Monitoring and supportive care to prevent and manage chemotherapy toxicity are available.**

All three are options: radiotherapy plus cisplatin with dose adjustment, radiotherapy plus a cisplatin substitute, and radiotherapy without chemotherapy.

Adding cisplatin to radiotherapy gives the best chances for survival and disease control, at the cost of increased chances of severe vomiting. It seems well-tolerated by elderly. Information about patients with kidney problems is limited.

Adding carboplatin to radiotherapy gives lower chances for survival and disease control. It decreases white blood cells placing the patient at risk for serious infection. It seems well-tolerated by patients with kidney problems, but less by the elderly.

Giving radiotherapy alone gives lower chances for survival and disease control. The side effects are usually milder than when chemotherapy is added.

The best option depends on the doctor's overall evaluation of the patient's medical condition and the patient's evaluation of her values, preferences and resources.

Part 4.

What are your feelings about your health, treatment, and situation?

Please check the corresponding box of your choice.

| <i>Compared to other women your age,</i> | A Lot Worse | Worse | Average | Better | A Lot Better |
|---|--------------------|--------------|----------------|---------------|---------------------|
| 1. How would you rate your current state of physical health (performing daily tasks)? | | | | | |
| 2. How would you rate your current state of emotional health (handling emotions)? | | | | | |
| 3. How would you rate your current state of social health (handling social roles and relationships)? | | | | | |
| 4. How would you rate your current state of mental health (thinking and making decisions)? | | | | | |
| 5. How would you rate your current state of overall health ? | | | | | |

| <i>How do you feel about the following statements?</i> | Strongly Disagree | Disagree | Unsure | Agree | Strongly Agree |
|---|--------------------------|-----------------|---------------|--------------|-----------------------|
| 6. I want to do everything possible to treat the cervical cancer. | | | | | |
| 7. I feel ready to deal with the possible side effects of chemotherapy. | | | | | |
| 8. For my sake, I am willing to receive chemotherapy. | | | | | |
| 9. For the sake of my family and important others, I am willing to receive chemotherapy. | | | | | |
| 10. I feel that my family and important others mostly believe that I should receive chemotherapy. | | | | | |
| 11. I feel pressure from my family and important others to receive chemotherapy. | | | | | |

| <i>If you decide to get chemotherapy, how would you feel about the following statements?</i> | Strongly Disagree | Disagree | Unsure | Agree | Strongly Agree |
|--|--------------------------|-----------------|---------------|--------------|-----------------------|
| 12. I feel confident about understanding and remembering information about my treatment. | | | | | |

| | | | | | |
|--|--|--|--|--|--|
| <i>13. I feel confident about applying information and following instructions about my treatment.</i> | | | | | |
| <i>14. I would probably need no or minimal support with performing my basic tasks of daily living.</i> | | | | | |
| <i>15. I would probably need no or minimal support with coping with chemotherapy.</i> | | | | | |
| <i>16. I would probably need no or minimal support with paying for the additional costs of chemotherapy and for the treatment of its toxicity.</i> | | | | | |

| <i>If you decide to get chemotherapy, how would you feel about the following statements?</i> | Strongly Disagree | Disagree | Unsure | Agree | Strongly Agree |
|--|--------------------------|-----------------|---------------|--------------|-----------------------|
| <i>17. My family or important others could help me understand and remember information about my treatment.</i> | | | | | |
| <i>18. My family or important others could help me apply information and follow instructions about my treatment.</i> | | | | | |
| <i>19. My family or important others could help me with my basic tasks of daily living.</i> | | | | | |
| <i>20. My family or important others could help me with coping with chemotherapy.</i> | | | | | |
| <i>21. My family or important others could help me with paying for the additional costs of chemotherapy and treatment of its toxicity.</i> | | | | | |

| <i>How do you feel about the following statements?</i> | Strongly Disagree | Disagree | Unsure | Agree | Strongly Agree |
|--|--------------------------|-----------------|---------------|--------------|-----------------------|
| <i>22. I feel confident about getting information to guide decisions about my cervical cancer and treatment.</i> | | | | | |
| <i>23. I feel confident about making decisions about my cervical cancer treatment.</i> | | | | | |

| |
|--|
| <i>24. Which statement below best describes your feelings about decisions about your health?</i> |
|--|

| | |
|--|--|
| | <i>I feel that I should have full control over decisions about my cervical cancer treatment.</i> |
| | <i>I would be more comfortable if I and my family and important others together decide about my cervical cancer treatment.</i> |
| | <i>I would be more comfortable if I and my doctors together decide about my cervical cancer treatment.</i> |
| | <i>I would be more comfortable if I, my family and important others, and my doctors all decide about my cervical cancer treatment.</i> |
| | <i>I prefer to leave to my family and important others any decision about my cervical cancer treatment.</i> |
| | <i>I prefer to leave to my doctors any decision about my cervical cancer treatment.</i> |

How do you feel about your decision now?

Please check the corresponding box of your choice.

| | Strongly Disagree | Disagree | Unsure | Agree | Strongly Agree |
|--|-------------------|----------|--------|-------|----------------|
| 1. I am willing to get chemotherapy. | | | | | |
| 2. I understand the available treatment options for me. | | | | | |
| 3. The benefits and side effects of the treatment options are clear to me. | | | | | |
| 4. I have enough support and advice from others to decide. | | | | | |

5. Which of the following best describes your **decision** now?

- I want to learn more about my treatment options.
- I understand my options and want to discuss them with others.
- I am decided but will need to evaluate my resources and plan.
- I am decided and am ready to get the treatment.

Part 5.

What's next?

1. Go back to Part 4.

| | If your marks are mostly to the LEFT of the middle | If your marks are mostly to the RIGHT of the middle |
|------------------------|---|---|
| Health | | |
| Items 1-5 | <ul style="list-style-type: none"> You feel mostly in poor health, which could be a reason not to get chemotherapy. | <ul style="list-style-type: none"> You feel mostly in good health, which could be a reason to get chemotherapy. |
| Personal Values | | |
| Items 6-11 | <ul style="list-style-type: none"> You have more reasons not to get chemotherapy. | <ul style="list-style-type: none"> You have more reasons to get chemotherapy. |
| Independence | | |
| Items 12-16 | <ul style="list-style-type: none"> You are more likely to cope poorly with getting chemotherapy. You may need to review your resources to see whether you have the help that you will need to cope well. | <ul style="list-style-type: none"> You are more likely to cope well with getting chemotherapy, which could be a reason to get chemotherapy. |
| Resources | | |
| Items 17-21 | <ul style="list-style-type: none"> You have limited support with getting chemotherapy. You may need to discuss this with your family, important others, and doctor to find out how you could get more support. | <ul style="list-style-type: none"> You have good support with getting chemotherapy, which could be a reason to get chemotherapy. |

| If your marks are mostly in the MIDDLE |
|--|
| <ul style="list-style-type: none"> Your overall personal situation and preference do not favor any one decision. You may need to examine your preferences for decision-making and decide about how much you would like to involve your doctor, family and important others in the process. |

| Preferences for Decision-Making | |
|--|---|
| Items 22-24 | <ul style="list-style-type: none"> These items help you reflect on your confidence and preferences in decision-making. |

- Go back to Part 3. Which items have you misunderstood?
- Go back to Part 2. Make a list of things that remain unclear to you or other things that you would want to discuss further with your doctor during your next visit.
- You can go through the material more than once until you feel that you are confident about your decision.
- Once you are confident about your decision, discuss a plan with your family and doctor regarding how to proceed with the treatment.