

The Use of Systemic Immunomodulating Drugs in Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis among Dermatologists in the Philippines: A Cross-sectional survey study

* Indicates required question

1. Email *

2. Informed Consent



This information sheet contains information regarding the nature of the study, which will be provided to all the subjects participating in the research.

Title: The Use of Systemic Immunomodulating Drugs in Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis among Dermatologists in the Philippines: A Cross-sectional survey study

Principal Investigator: Ivan Arni C. Preclaro, MD

Co-author/s: Michaela Tabalon-Morales, MD, Ma. Corazon Iniego-Rodas, MD, Lian C. Jamisola, MD

A copy of the informed consent will be provided.

Part I. Information Sheet

Information Sheet

I am Dr. Ivan Arni C. Preclaro, a Medical Specialist in Dermatology at the Tondo Medical Center. I am doing a study on **The Use of Systemic Immunomodulating Drugs in Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis among Dermatologists in the Philippines: A Cross-sectional survey study**

I am going to explain to you what the study is about and if you are willing to give your consent, I would like to invite you to be part of this study. Before you decide, you can think or talk to anyone you feel comfortable with regarding the research. If there are some words that you do not understand, kindly let me know and I will try

to explain further. If you have other questions later, I will also be happy to answer them as well.

Introduction

This research will assess the variation of preferred medical practices for Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis among board-certified dermatologists in the Philippines.

Purpose of the Research

The study will primarily benefit the Philippine Dermatological Society in establishing consensus guidelines in the management of Stevens-Johnson Syndrome/ Toxic Epidermal Necrolysis in the Philippines. Aside from that, studies on clinical trials for potential medical therapies may promote collaboration with dermatologists in the Philippines.

Type of Research Intervention

The study will be a descriptive cross sectional study design using online survey

Participant Selection

Participants that will be diplomates and fellows who are board-certified dermatologists of the Philippine Dermatological Society in the Philippines with a minimum of 297.

Voluntary Participation

Your participation in this research is purely voluntary. If you choose not to join this research, we assure the confidentiality of the information you disclosed to us. If you choose to join this research but later change your mind, you may withdraw even if you agreed earlier

Procedures and Protocol

Once you have agreed and signed on this informed consent, you will be answering an online survey form.

Duration of the Study

The study will actively search for a board-certified dermatologist in an estimate period of 1-2 months

Risks

There are no known serious risks identified with participation in this study.

Benefits

This study will help in assessing the variation of preferred medical practices and development of future consensus guidelines for Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis among board-certified dermatologists in the Philippines.

Reimbursements

You will not be given any monetary incentives to take part in this study.

Confidentiality

Your information and data in this study will be kept confidential. Participants will be assigned a designated code e.g Case participant number 1: A-001 that will be used for the entire study and documentation, and only the investigator will be able to see it. The REC and regulatory authorities will be granted direct access to participant's medical records for purposes only of verification of clinical trial procedures and data.

Sharing the Results

The knowledge we will get from this research will be shared with you at the end of the study period. Confidential information, however, will not be shared.

Subsequently, the results may be presented in conferences or published in journals so that other interested people may learn from this study.

Right to Refuse or Withdraw

In case that you do not want to participate in this research in whatever personal or other reasons at any time you may refuse to. In case that you consent to participate in the study initially and in the middle of the study you wish to terminate your participation and withdraw all the data and information pertaining to the subject, you may do so, just inform the investigator.

Investigator's Responsibility

The investigator will be responsible for identifying, documenting and reporting all the data. He will only serve as an investigator and not the health care provider.

Participant's Responsibility

The participant has the responsibility to respect the investigators, personnel related to the study and other participants, to read thoroughly the consent form and other documents related, to ask clarifications and questions, if need be, and to keep the staff informed of any changes on the contact number or address.

Alternative to Participating

None

Whom to Contact

If you have any questions regarding the study, you may ask now or anytime during the course of the study. If you have any questions that might occur later in the study you may contact Tondo Medical Center- Department of Dermatology and Venereology through (8865-9000 local 1093) and the investigator's contact number

(09173259264). For grievances and complaints as well as information on the rights of study participants you may reach through the Research Ethics Committee of Tondo Medical Center

Whom to Contact

Whom can I contact if I have any questions or concerns?

If you wish to ask questions later, you may contact the principal investigator:

Ivan Arni C. Preclaro, MD, DPDS, DDSP-PDS, FAADV (Dermopath.)

Medical Specialist, Department of Dermatology and Venereology, Tondo Medical Center

09173259264

preclaro.ic.s@slmc-cm.edu.ph

If you have any complaints or questions about your rights as a research volunteer, you may also contact the Institutional Review Board:

Paul John L. Ablaza, MD, FPCP, FPCC, FPSE

Chair, Research Ethics Committee

Tondo Medical Center

plablaza@ust.edu.ph

09328488082

8865-9000 loc 1069

Mark only one oval.

- ☐ I have read the document above. I understand the purpose of this study. I freely give my consent to join in this study.
- ☐ I do not give my consent to participate in this study.
Skip to section 10 (Last Section)

Untitled Section

3. Please write the COMPLETE name of the medical institution/hospital you are associated with. *

4. In what year did you complete your dermatology residency? *

5. How many patients have you treated for Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, or SJS/TEN overlap **in the past year?** *

Mark only one oval.

- ☐ None
- ☐ 1-5
- ☐ 6-10
- ☐ 11-15
- ☐ 16+

6. What percentage of your patient care time is spent on **inpatient service**? *

Mark only one oval.

- ☐ 0%
- ☐ 10%
- ☐ 20%
- ☐ 30%
- ☐ 40%
- ☐ 50%
- ☐ 60%
- ☐ 70%
- ☐ 80%
- ☐ 90%
- ☐ 100%

Clinical Vignette 1

30-year-old previously healthy male, with **biopsy**

proven Stevens Johnson Syndrome that developed 2 weeks after starting anti-epileptic therapy

- **5% body surface area** of detached skin (BSA only includes skin that was already necrotic, detached, or skin with positive Nikolsky sign)

- Symptoms **started 48 hours prior** to admission

-Currently admitted to **MICU**

-No other medical comorbidities

-Patient and primary team are open to all medical interventions

Besides STOPPING THE CURRENT MEDICATIONS and SUPPORTIVE CARE, please rank as many preferred treatment modalities for this patient as you'd like, with the top listed choice as your #10 (HIGHEST) preferred treatment.

*IF THE MEDICATION IS NOT PREFERRED, PLEASE RANK THEM '0'

7. Corticosteroids *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. CycloPHOSphamide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

9. CycloSPORine *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

10. Granulocyte colony stimulating factor *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

11. Intravenous Immunoglobulin *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

12. Plasmapheresis *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

13. Thalidomide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

14. TNF inhibitors *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

15. Other medications *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

16. For "OTHER" medications, please indicate which agent you will use. Please put N/A if none *

17. Combined medical therapy *

Mark only one oval.

0 1 2 3 4 5 6 7 8 9 10

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

18. For "COMBINED MEDICAL THERAPY" medications, please indicate which agents you will use. Please put N/A if none *

Clinical Vignette 2

Imagine

everything is the same as the original clinical vignettes (**30 yo, 5% BSA, 48 hours prior, MICU**), but on exam she has conjunctival injection and describes "gritty sensation" in her eyes. Ophthalmology is consulted and confirms she has **ocular mucosal involvement**.

Besides STOPPING THE CURRENT MEDICATIONS and SUPPORTIVE CARE, please rank as many preferred treatment modalities for this patient as you'd like, with the top listed choice as your #10 (HIGHEST) preferred treatment.

***IF THE MEDICATION IS NOT PREFERRED, PLEASE RANK THEM '0'**

19. Corticosteroids *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

20. CycloPHOSphamide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

21. CycloSPORine *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

22. Granulocyte colony stimulating factor *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

23. Intravenous Immunoglobulin *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

24. Plasmapheresis *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

25. Thalidomide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

26. TNF inhibitors *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

27. Other medications *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

28. For "OTHER" medications, please indicate which agent you will use. Please put N/A if none *

29. Combined medical therapy *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

30. For "COMBINED MEDICAL THERAPY" medications, please indicate which agents you will use. Please put N/A if none *

Clinical Vignette 3

Imagine

everything is the same as the original clinical vignettes (**30 yo, 5% BSA, 48 hours prior, MICU**), but this patient also has **Chronic Kidney Disease Stage II eGFR 65 (NO ocular involvement)**.

Besides STOPPING THE CURRENT MEDICATIONS and SUPPORTIVE CARE, please rank as many preferred treatment modalities for this patient as you'd like, with the top listed choice as your #10 (HIGHEST) preferred treatment.

***IF THE MEDICATION IS NOT PREFERRED, PLEASE RANK THEM '0'**

31. Corticosteroids *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

32. CycloPHOSphamide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

33. CycloSPORine *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

34. Granulocyte colony stimulating factor *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

35. Intravenous Immunoglobulin *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

36. Plasmapheresis *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

37. Thalidomide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

38. TNF inhibitors *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

39. Other medications *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

40. For "OTHER" medications, please indicate which agent you will use. Please put N/A if none *

41. Combined medical therapy *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

42. For "COMBINED MEDICAL THERAPY" medications, please indicate which agents you will use. Please put N/A if none *

Clinical vignette 4

Imagine everything is the same as the original clinical vignettes (**30 yo, 5% BSA, 48 hours prior, MICU**), but this patient also has **ESRD on hemodialysis (NO ocular involvement)**.

Besides STOPPING THE CURRENT MEDICATIONS and SUPPORTIVE CARE, please rank as many preferred treatment modalities for this patient as you'd like, with the top listed choice as your #10 (HIGHEST) preferred treatment.

***IF THE MEDICATION IS NOT PREFERRED, PLEASE RANK THEM '0'**

43. Corticosteroids *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

44. CycloPHOSphamide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

45. CycloSPORine *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

46. Granulocyte colony stimulating factor *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

47. Intravenous Immunoglobulin *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

48. Plasmapheresis *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

49. Thalidomide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

50. TNF inhibitors *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

51. Other medications *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

52. For "OTHER" medications, please indicate which agent you will use. Please put N/A if none *

53. Combined medical therapy *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

54. For "COMBINED MEDICAL THERAPY" medications, please indicate which agents you will use. Please put N/A if none *

Clinical Vignette 5

Imagine everything is the same as the original clinical vignettes (**i.e. no ocular involvement or CKD**), but involved **BSA is >30%**. (BSA only includes skin that is already necrotic, detached, or skin with positive Nikolsky sign).

Besides STOPPING THE CURRENT MEDICATIONS and SUPPORTIVE CARE, please rank as many preferred treatment modalities for this patient as you'd like, with the top listed choice as your #10 (HIGHEST) preferred treatment.

***IF THE MEDICATION IS NOT PREFERRED, PLEASE RANK THEM '0'**

55. Corticosteroids *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

56. CycloPHOSphamide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

57. CycloSPORine *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

58. Granulocyte colony stimulating factor *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

59. Intravenous Immunoglobulin *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

60. Plasmapheresis *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

61. Thalidomide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

62. TNF inhibitors *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

63. Other medications *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

64. For "OTHER" medications, please indicate which agent you will use. Please put N/A if none *

65. Combined medical therapy *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

66. For "COMBINED MEDICAL THERAPY" medications, please indicate which agents you will use. Please put N/A if none *

Clinical Vignette 6

Imagine

everything is the same as the **PREVIOUS** clinical vignettes (**i.e.**

BSA>30%, no ocular involvement or CKD), but but this patient has **suspected bacteremia** and has been started on **empiric broad-spectrum antibiotics**.

Besides stopping the current medications and supportive care, please rank as many preferred treatment modalities for this patient as you'd like, with the top listed choice as your #10 (HIGHEST) preferred treatment.

***IF THE MEDICATION IS NOT PREFERRED, PLEASE RANK THEM '0'**

67. Corticosteroids *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

68. CycloPHOSphamide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

69. CycloSPORine *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

70. Granulocyte colony stimulating factor *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

71. Intravenous Immunoglobulin *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

72. Plasmapheresis *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

73. Thalidomide *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

74. TNF inhibitors *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

75. Other medications *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

76. For "OTHER" medications, please indicate which agent you will use. Please put N/A if none *

77. Combined medical therapy *

Mark only one oval.

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

78. For "COMBINED MEDICAL THERAPY" medications, please indicate which agents you will use. Please put N/A if none *

Untitled Section

79. In our scenarios, the symptom onset was 48 hours (2 days) prior. After how many days from symptom onset would you **NO LONGER CONSIDER** treatment with active pharmacology? *
-

80. When consulted for cases of confirmed SJS/TEN, how often do you recommend consults with the following teams as part of your treatment plan? *

Mark only one oval per row.

	Never	Rarely	Sometimes	Most of the time	Always
Ophthalmology	☐	☐	☐	☐	☐
Gynecology (female only)	☐	☐	☐	☐	☐
Otorhinolaryngology	☐	☐	☐	☐	☐
Urology	☐	☐	☐	☐	☐

81. Which of the following treatment options have you used within the past 5 years for * treating a patient of suspected or confirmed SJS/TEN? Please choose all that apply.

If you had no SJS/TEN case in the said time period, choose N/A

Check all that apply.

- ☐ Corticosteroids
- ☐ CycloPHOSphamide
- ☐ CycloSPORine
- ☐ Granulocyte colony stimulating factor
- ☐ Hemoperfusion
- ☐ Intravenous Immunoglobulin
- ☐ Plasmapheresis
- ☐ Supportive care only
- ☐ Thalidomide
- ☐ TNF-alpha inhibitors
- ☐ Other
- ☐ N/A

82. If **corticosteroids** was chosen, please write the **name** of each type of **STEROID** * you have used, followed by the **route of administration**, **dose** (or range of doses), and **duration** (or range of durations) of therapy.

Ex. Dexamethasone 100 mg PO daily for 4 days

Methylprednisone 30 mg/kg IV Q6 hours for 3 days

Please put N/A if not chosen.

83. If **cycloPHOSphamide** was chosen, please write the **route of administration**, **dose** (or range of doses), and **duration** (or range of durations) of therapy. *

Please put N/A if not chosen.

84. If **cycloSPORin** was chosen, please write the **route of administration**, **dose** (or **range of doses**), and **duration** (or range of durations) of therapy. *

Please put N/A if not chosen.

85. If **granulocyte colony stimulating factor** was chosen, please write the **route of administration**, **dose** (or range of doses), and **duration** (or range of durations) of therapy. *

Please put N/A if not chosen.

86. If **Intravenous Immunoglobulin** was chosen, please write the **route of administration**, **dose** (or range of doses), and **duration** (or range of durations) of therapy. *

Please put N/A if not chosen.

87. If **TNF-alpha inhibitor** was chosen, please write the **name** of each **TNF inhibitor** you have used, followed by the **route of administration**, **dose** (or range of doses), and **duration** (or range of durations) of therapy.. *

Please put N/A if not chosen.

88. If **other** was chosen, please write the **name of other** you have used, followed by **the route of administration, dose** (or range of doses), and **duration** (or range of durations) of therapy.. *

Please put N/A if not chosen.

89. Any additional feedback or information you would like us to know? *

Last Section

Thank you for your participation in this study. We hope to hear from you again in our succeeding research projects.

Ivan Arni C. Preclaro, MD
Michaela Tabalon-Morales, MD
Maria Corazon Iniego-Rodas, MD
Lian C. Jamisola, MD

DOH- Tondo Medical Center
Department of Dermatology and Venereology
Balut, Tondo, Manila

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