

# BREAK OUT SESSION: PLAIN LANGUAGE TECHNIQUES

Tips & tools for creating clear communication that reaches past health literacy barriers.



Bran LeFae  
Medical Writer, Seattle Genetics

*All opinions expressed in the course of this presentation are mine alone. This presentation does not include any information about current Seattle Genetics practices.*

# Learning Objectives

## I. Health Literacy & Plain Language

*Review health literacy needs and how plain language addresses them*

## II. Plain Language for Readability

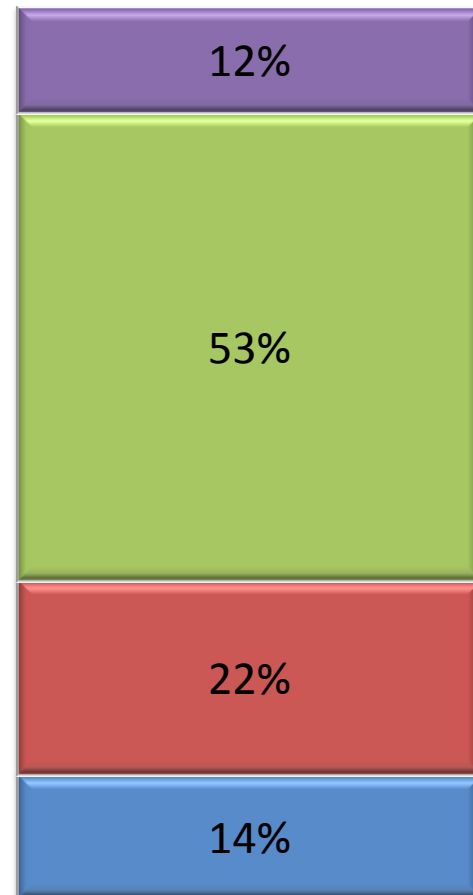
*Discuss the components of plain language that impact reading ease*

## III. Plain Language Techniques

*Work individually or with a partner to edit real consent form text using plain language techniques*

# Health Literacy Levels (United States)<sup>7</sup>

- Proficient
- Intermediate
- Basic
- Below Basic



# Health Literacy Levels Defined

**Proficient:** Can find information in long, complicated, abstract writing, and can make complex inferences. Can perform more complicated, challenging literacy activities. **(12%)**

**Intermediate:** Can perform moderately challenging literacy activities. Can find information in denser, less simply written text. Can make simple inferences about information. **(53%)**

**Basic:** Can perform simple, everyday literacy activities. Can find information and follow instructions when written simply. **(22%)**

**Below Basic:** Can find information and follow instructions when written simply. Very concrete health literacy skills. **(14%)**

# Health Literacy Levels in Europe<sup>8</sup>

“Nearly half of all Europeans have inadequate and problematic health literacy skills.”

- Low literacy levels are common
- Limited health literacy is very common
- Health literacy levels vary greatly between European countries

Some groups are more vulnerable.

- Lower social status/education level/income, especially those with worse health status
- Older people

# What is Plain Language?

**Plain language does not “dumb down” communication.**

It uses specific techniques to keep content on point and remove extraneous details.

Plain language reaches past health literacy barriers with effective, clear communication that respects the audience and meets their needs.



# Plain Language is Clear Communication

In plain  
language  
writing, we:

- write in the first person and active voice to engage our reader
- use a conversational style with common words
- write in short sentences of varying lengths for better flow
- keep it to one point per paragraph and limit unnecessary details in the content
- format for readability

# Simple, Direct Communication

## Use simple language

- Conversational style
- Common words, minimal jargon
- First person (I, we)
- Active voice (sentence subject performs the action)



Example

We are asking you to think about taking part in a research study.



# Engage the Brain!

Keep the reader engaged and avoid reading fatigue

- Use short sentences of varying lengths
- Try to keep your sentences to 15 words or less

## Example

We are asking you to take part in this study because you have bladder cancer. (15) Your cancer has grown worse or come back after being treated. (11) You have also been treated with a certain type of drug, called a checkpoint inhibitor. (15) We are studying a new treatment for patients like you. (10)

# Keep it Focused and Guide the Reader

Chunk your information – it will be digested better if it's organized around a central concept and kept clear.

Think appetizers, not a five course meal.

- One point per paragraph
- Limit unnecessary details

Format your information with consistent headers and sub-headings. These are guideposts to help the eye travel through the document.

- Bold or italic font draws attention
- Don't use all capital letters – this is less readable

# Reading Level and Reading Ease

There are two measurements, easily available in Microsoft Word, that you can use to see how easy it is to read a document. They are a rough measurement with some limitations.

- Flesch-Kincaid Reading Level
- Flesch-Kincaid Reading Ease

The reading level measurement uses the United States school grade system to look at readability.

**Adjust for your audience.**

The reading ease measurement comes from the number of syllables per word and number of words per sentence.

**Aim for 70 or higher.**

# Turning on Flesch-Kincaid in Microsoft Word:

File tab → Options → Proofing

Turn on Flesch-Kincaid...and while you're at it, turn on Grammar check.

## When correcting spelling and grammar in Word

- Check spelling as you type
- Use contextual spelling
- Mark grammar errors as you type
- Check grammar with spelling
- Show readability statistics

Writing Style: Grammar & Style

## Writing style:

Grammar & Style

## Grammar and style options:

- Relative clauses
- Subject-verb agreement
- Verb phrases

## Style:

- Clichés, Colloquialisms, and Jargon
- Contractions
- Fragment - stylistic suggestions
- Gender-specific words
- Hyphenated and compound words
- Misused words - stylistic suggestions
- Numbers
- Passive sentences

Turn off contractions for conversational style writing

Turn on passive sentence detection

# Reading Ease

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## Reading ease levels:

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90 – 100 = Very easy

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80 – 89 = Easy

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 70 – 79 = Fairly easy

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60 – 69 = Standard

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50 – 59 = Fairly difficult

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30 – 49 = Difficult

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0 – 29 = Very confusing

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# Use This Tool Wisely!

This tool is only part of the tool kit.

Use it with plain language techniques and common sense.

Flesh-Kincaid uses specific factors to measure readability:

1. Length of sentences
2. Length of the words in the sentences

## Pluses

Good tool for the big picture

Allows you to see a quantitative improvement in readability

## Minuses

Limited because it only uses quantitative factors

Doesn't measure things like white space or formatting that contribute to readability

# LET'S GET STARTED!

In our first example, we'll tackle:

- ✓ First person and active voice
- ✓ Conversational style and common words

# Starting Text

If you remain on the study drug until the end of the study, you will need to return to the study center for an End of Study Visit. Prior to this visit, you may be offered enrollment in an optional open-label extension study in which the study drug may be provided to you until the drug is approved or until the study is stopped. If you chose not take part in the open-label extension study, this visit will occur after you have been completely taken off study drug. You will be slowly taken off study drug either by one tablet four times a day or week, as determined by your study doctor. If you choose to take part in the open-label extension study, you will remain on study drug for this visit. During this visit, you will be asked to sign a separate consent form for the open-label extension study.



Flesch-Kincaid

Reading Grade Level: 11.5

Reading Ease: 56.8 (fairly difficult)



# Identifying Second Person, Passive Voice

If **you** remain on the study drug until the end of the study, **you will need** to return to the study center for an End of Study Visit. Prior to this visit, **you may be** offered enrollment in an optional open-label extension study in which the study drug **may be provided** to **you** until the drug **is approved** or until the study **is stopped**. If **you** chose not take part in the open-label extension study, this visit **will occur** after **you have been** completely taken off study drug. **You will be** slowly taken off study drug either by one tablet four times a day or week, as determined by your study doctor. If **you** choose to take part in the open-label extension study, **you will** remain on study drug for this visit. During this visit, **you will be** asked to sign a separate consent form for the open-label extension study.

# Writing in First Person, Active Voice

If you remain on the study drug until the end of the study, **we will ask you** to return to the study center for an End of Study Visit. Prior to this visit, **we may offer you offered** enrollment in an optional open-label extension study in which **we may provide** the study drug to you until the drug is approved or until the study **stops**. If you chose not take part in the open-label extension study, **we will ask you to come for** this visit after **we take you completely**~~have been completely taken~~ off study drug. **We will** slowly ~~taken~~ **take you** off study drug either by one tablet four times a day or week, as determined by your study doctor. If you choose to take part in the open-label extension study, **we will remain** ~~have you stay~~ on study drug for this visit. During this visit, **we will ask you asked** to sign a separate consent form for the open-label extension study.

Flesch-Kincaid

Reading Grade Level: ~~11.5~~ **11.3**

Reading Ease: ~~56.8 (fairly difficult)~~ **60 (standard)**

# Identifying Areas for Conversational Style, Reducing Jargon

If you **remain** on the study drug until the end of the study, we will ask you to **return to the study center** for an **End of Study Visit**. **Prior** to this visit, we may offer you **enrollment** in an **optional open-label extension study** in which we may provide the study drug to you until the drug is approved or until the study stops. If you chose not take part in the **open-label extension study**, we will ask you to come for this visit after we take you **completely** off study drug. We will slowly take you off study drug either by one tablet four times a day or week, as **determined** by your study doctor. If you choose to take part in the **open-label extension study**, we will have you stay on study drug for this visit. During this visit, we will ask you to sign a separate consent form for the **open-label extension study**.

## Goals

Use common terms, reduce multisyllabic words and jargon.

# Writing in a Conversational Style with Common Words

If you **stay** on the study drug until the end of the study, we will ask you to **come back** for ~~an~~ **a final visit**. **Before** ~~to~~-this visit, we may offer you **a chance to take part** in ~~an~~ **another study** in which we may provide the study drug to you until the drug is approved or until the study stops. If you chose not take part in the **other study**, we will ask you to come for this visit after we take you off study drug. We will slowly take you off study drug either by one tablet four times a day or week, as **decided** by your study doctor. If you choose to take part in the **other study**, we will have you stay on study drug for this visit. During this visit, we will ask you to sign a separate consent form for the **other study**.

Flesch-Kincaid

Reading Grade Level: ~~11.5~~ ~~11.3~~ **9.0**

Reading Ease: ~~56.8 (fairly difficult)~~ ~~60 (standard)~~ **73.7 (fairly easy)**

# Editing Exercise #1 (10 minutes)

Edit for

First person, active voice  
Conversational style, common terms

If you were already taking study drug prior to screening for this study, you will receive a new study drug starter kit (which contains an inhalation device and medication) which will last up until your Week 4 Visit. You will be instructed to discontinue the use of the study drug inhalation devices you had before the start of the study and the site will collect these devices from you at this visit. The new study drug inhalation device and medication that is provided in the study drug starter kit is what you are to use during the course of this study. A Specialty Pharmacy representative will contact you directly to set up the resupply of your study drug medication that will be used during the course of this study at no cost to you.

# Editing Exercise #1 (10 minutes)

If **you** were already taking study drug **prior** to **screening** for this study, **you will receive** a new study drug starter kit (which contains an **inhalation device** and medication) which will last up until your **Week 4 Visit**. **You will be instructed** to **discontinue** the use of the study drug **inhalation devices** **you** had before the start of the study and the site **will collect** these devices from **you** at this visit. The new study drug **inhalation device** and medication that **is provided** in the study drug starter kit is what **you** are to use **during the course** of this study. A **Specialty Pharmacy representative** **will contact** **you** directly to set up the **resupply** of your study drug medication that **will be used** **during the course** of this study at no cost to **you**.

Second person, passive voice

Conversational, common words



Flesch-Kincaid

Reading Grade Level: 15.2  
Reading Ease: 45.3 (difficult)

# Identifying Long Sentences and Natural Breaks

If you stay on the study drug until the end of the study, **we will ask you** to come back for a final visit (24). Before this visit, **we may offer you** a chance to take part in another study in which we may provide the study drug to you **until** the drug is approved **or** until the study stops (35). If you chose not take part in the other study, **we will ask you** to come for this visit **after** we take you off study drug (26). We will slowly take you off study drug either by one tablet four times a day or week, **as decided by** your study doctor (24). If you choose to take part in the other study, **we will have you** stay on study drug for this visit (21). During this visit, **we will ask you** to sign a separate consent form for the other study (17).

## Tip

Look for commas, semi-colons, and places where sentences join through conjunctions (and, or, but, etc.)

# Writing Short Sentences of Varying Lengths (15 words or less)

If you take the study drug until the study ends, we will ask you to come for a final visit (20). We may offer you a chance to take part in another study (12). This would allow us to give you the study drug after you're done with this study (16). We can do this until the drug is approved or the other study stops (14). If you don't want to be in the other study, we will slowly cut down the amount of study drug (20). We'll ask you to come for the final visit after you're done taking the drug (15). Your doctor will decide one of two ways to take you off of the drug (15). We will either cut down by one tablet four times a day or four times a week (17). If you choose to take part in the other study, you will keep taking the study drug (17). We will ask you to sign a new consent form for the other study at your last visit (17).

Flesch-  
Kincaid

Reading Grade Level: ~~11.5~~ ~~11.3~~ ~~9.0~~ 5.4

Reading Ease: ~~56.8 (fairly difficult)~~ 60 (standard) ~~73.7 (fairly easy)~~ 84.9 (easy)



# Editing Exercise #2 (10 minutes)

Edit for

Shorter sentences, 15 words or less

If you were already taking study drug prior to screening for this study, you will receive a new study drug starter kit (which contains an inhalation device and medication) which will last up until your Week 4 Visit. You will be instructed to discontinue the use of the study drug inhalation devices you had before the start of the study and the site will collect these devices from you at this visit. The new study drug inhalation device and medication that is provided in the study drug starter kit is what you are to use during the course of this study. A Specialty Pharmacy representative will contact you directly to set up the resupply of your study drug medication that will be used during the course of this study at no cost to you.

# Editing Exercise #2 (10 minutes)

If you were already taking study drug prior to screening for this study, you will receive a new study drug starter kit (which contains an inhalation device and medication) which will last up until your Week 4 Visit. (38) You will be instructed to discontinue the use of the study drug inhalation devices you had before the start of the study and the site will collect these devices from you at this visit. (34) The new study drug inhalation device and medication that is provided in the study drug starter kit is what you are to use during the course of this study. (29) A Specialty Pharmacy representative will contact you directly to set up the resupply of your study drug medication that will be used during the course of this study at no cost to you. (33)

# Identifying Multiple Points per Paragraph

If you take the study drug until the study ends, we will ask you to come for a final visit. We may offer you a chance to take part in another study. This would allow us to give you the study drug after you're done with this study. We can do this until the drug is approved or the other study stops. If you don't want to be in the other study, we will slowly cut down the amount of study drug. We'll ask you to come for the final visit after you're done taking the drug. Your doctor will decide one of two ways to take you off of the drug. We will either cut down by one tablet four times a day or four times a week. If you choose to take part in the other study, you will keep taking the study drug. We will ask you to sign a new consent form for the other study at your last visit.

## Note

This paragraph is not organized with a logical flow, which makes it difficult to understand in the first place. It also contains multiple points.

# Writing With a Single Point per Paragraph

If you take the study drug until the study ends, we will ask you to come for a final visit.

We may offer you a chance to take part in another study. This would allow us to give you the study drug after you're done with this study. We can do this until the drug is approved or the other study stops. If you choose to take part in the other study, you will keep taking the study drug. We will ask you to sign a new consent form for the other study at your last visit.

If you don't want to be in the other study, we will slowly cut down the amount of study drug. Your doctor will decide one of two ways to take you off of the drug. We will either cut down by one tablet four times a day or four times a week. We'll ask you to come for the final visit after you're done taking the drug.

# Editing Exercise #3 (10 minutes)

Edit for

Single point per paragraph

If you were already taking study drug prior to screening for this study, you will receive a new study drug starter kit (which contains an inhalation device and medication) which will last up until your Week 4 Visit. You will be instructed to discontinue the use of the study drug inhalation devices you had before the start of the study and the site will collect these devices from you at this visit. The new study drug inhalation device and medication that is provided in the study drug starter kit is what you are to use during the course of this study. A Specialty Pharmacy representative will contact you directly to set up the resupply of your study drug medication that will be used during the course of this study at no cost to you.

# Editing Exercise #3 (10 minutes)

If you were already taking study drug prior to screening for this study, you will receive a new study drug starter kit (which contains an inhalation device and medication) which will last up until your Week 4 Visit. You will be instructed to discontinue the use of the study drug inhalation devices you had before the start of the study and the site will collect these devices from you at this visit. The new study drug inhalation device and medication that is provided in the study drug starter kit is what you are to use during the course of this study. A Specialty Pharmacy representative will contact you directly to set up the resupply of your study drug medication that will be used during the course of this study at no cost to you.

# Limiting Details and Identifying Dense Text

After your Baseline Visit, you will receive weekly telephone calls from your study doctor's office up until your Week 12 Visit, except for Weeks 4 and 8 when you have clinic visits. During these calls, **you will be asked about any side effects you may have had, how you have been taking the study drug, study drug, and your other medications (prescription, over-the-counter drugs, vitamins or herbs) will be reviewed for any changes since your last visit/telephone call.**

After two weeks on study drug, you will receive a call from your study doctor's office to increase your study drug dose to two tablets four times a day. The decision to adjust your dose of the study drug dose will be determined during this call.



Flesch-Kincaid

Reading Grade Level: 13.8

Reading Ease: 51.2 (fairly difficult)

# Identifying Dense Text

After your Baseline Visit, you will receive weekly telephone calls from your study doctor's office up until your Week 12 Visit, except for Weeks 4 and 8 when you have clinic visits. **During these calls, you will be asked about**

- side effects
- how you have been taking the study drug
- other medications

After two weeks on study drug, you will receive a call from your study doctor's office. ~~to increase your study drug dose to two tablets four times a day.~~ The decision to adjust your dose to two tablets four times daily will be determined during this call.

Flesch-Kincaid

Reading Grade Level: ~~13.8~~ 10.3

Reading Ease: ~~51.2 (fairly difficult)~~ 60.1 (standard)



# Editing Exercise #4 (10 minutes)

## Edit for

Use formatting to break up dense text.  
Remove unnecessary details.

You should take your inhaled study drug as instructed four times per day. Inhalation sessions should take place during waking hours about 4 hours apart. You should take your study drug immediately before or after you take your study drug inhalation. You should take your study drug tablets four times per day with approximately 240 mL (8 ounces) of water. You should be careful not to break, chew, or disrupt the integrity of the tablet as this will result in inappropriate delivery of the study drug ingredient. If the tablet is damaged during administration, you should contact the study center personnel in order to be monitored for side effects due to possible overdose.

## Flesch-Kincaid

Reading Grade Level: 10.8  
Reading Ease: 50.7 (fairly difficult)

# Starting Text

If you remain on the study drug until the end of the study, you will need to return to the study center for an End of Study Visit. Prior to this visit, you may be offered enrollment in an optional open-label extension study in which the study drug may be provided to you until the drug is approved or until the study is stopped. If you chose not take part in the open-label extension study, this visit will occur after you have been completely taken off study drug. You will be slowly taken off study drug either by one tablet four times a day or week, as determined by your study doctor. If you choose to take part in the open-label extension study, you will remain on study drug for this visit. During this visit, you will be asked to sign a separate consent form for the open-label extension study.



Flesch-Kincaid

Reading Grade Level: 11.5

Reading Ease: 56.8 (fairly difficult)

# Final Text

If you take the study drug until the study ends, we will ask you to come for a final visit.

We may offer you a chance to take part in another study. This would allow us to give you the study drug after you're done with this study. We can do this until the drug is approved or the other study stops. If you choose to take part in the other study, you will keep taking the study drug. We will ask you to sign a new consent form for the other study at your last visit.

If you don't want to be in the other study, we will slowly cut down the amount of study drug. Your doctor will decide one of two ways to take you off of the drug. We will either cut down by one tablet four times a day or four times a week. We'll ask you to come for the final visit after you're done taking the drug.



Flesch-Kincaid

Reading Grade Level: 5.4  
Reading Ease: 84.9 (easy)

# Conclusions

I. Plain language writing and editing techniques can bridge the health literacy gap in written informed consent material.



II. Components of plain language include using active voice to engage the reader, conversational style with common words, short sentences of varying lengths for better flow, one point per paragraph to reduce unnecessary details, and effective formatting for readability.

# References

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8. World Health Organization, Regional Office for Europe. 2013. Health Literacy: The Solid Facts. World Health Organization

# Resources

Group Health Program for Readability in Science & Medicine (PRISM):

<https://www.grouphealthresearch.org/about-us/capabilities/research-communications/prism/>

Center for Plain Language:

<http://centerforplainlanguage.org/>

Plain Language at the NIH:

<https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/plain-language>

Plain Language at the CDC:

<http://www.cdc.gov/healthliteracy/developmaterials/PlainLanguage.html>

LinkedIn: Plain Language Association InterNational Group (PLAIN)

Questions?