

JDRF Artificial Pancreas Project Randomized Clinical Trial
Complication Utilities- Subject Version
tblASurveyComps

Patient ID: _____ **PtID**

COMPLICATION UTILITIES

Throughout this study, we have asked you to consider the quality of life effects of diabetes and its treatments. It is also important for us to understand how much of an impact different complications would have on your life. We will be asking you again the same type of imaginary questions we have asked during earlier parts of the study. If these questions make you uncomfortable, we may stop.

Interviewer:

The time tradeoff questions begin at this point.

Use the “Time frame” that corresponds to the age of the patient to select the correct the hierarchical diagrams beginning on page 4. The hierarchical diagram must be used in conjunction with every section below (*Blindness, Kidney Failure, Chest Pain Related to Heart Disease, Severe Stroke and Living Without Part of your Lower Leg*).

Age of patient	Time frame*	
8-15	50	} TimeFrameS
15-25	40	
25-35	30	
>35	20	

Note: The selected **Time frame will be used with the hierarchical diagrams beginning on page 4.*

The first question is simply a choice between the full time in current health vs. the full time in perfect health. If subject chooses full time in current health then discuss answer, determine if subject intends answer and go to next question. All questions are a choice between 1) “X years in perfect health” 2) “Y years with condition” or 3) “No preference, because these seem about the same”. The questions in every section (*Blindness, Kidney Failure,...*) must be asked six different times using the hierarchical diagram flow or until the patient chooses “No preference”. If this section is unclear please see example at the end of this document.

1. Blindness

Imagine a life with **blindness**:

- You would not be able to read, see the TV, or drive a car.
- You may also need assistance with many day-to-day tasks such as cooking, cleaning, dressing yourself, and bathing.
- You may also need assistance taking your medications.

Imagine you had the following choice, which would you prefer?

- | | | |
|--|---|-------------------------------|
| <input type="checkbox"/> ___ years living with blindness | } | BlindChoice1S, BlindChoice2S, |
| <input type="checkbox"/> ___ years in perfect health | | BlindChoice3S, BlindChoice4S, |
| <input type="checkbox"/> No preference, because these seem about the same to him/her | | BlindChoice5S BlindChoice6S |

- ☐ Subject refuses to continue 'blindness' question BlindRefContS

2. End-stage renal disease

Imagine a life with **kidney failure**:

- You would experience fatigue, bone problems, joint problems, itching, and 'restless legs'.
- You would need to have dialysis 3 times per week and this procedure usually lasts 3-5 hours. You may need to make changes in your work or home life to maintain this schedule.
- During dialysis you are attached to a machine. To do this, a needle is inserted into tubing that has been placed under the skin of your arm. The machine then filters the blood to get rid of waste products.
- You may sometimes feel sick or tired for a few hours after you have had dialysis.

Imagine you had the following choice, which would you prefer?

- | | | |
|--|---|-------------------------------|
| <input type="checkbox"/> ___ years living with kidney failure | } | RenalChoice1S, RenalChoice2S, |
| <input type="checkbox"/> ___ years in perfect health | | RenalChoice3S, RenalChoice4S, |
| <input type="checkbox"/> No preference, because these seem about the same to him/her | | RenalChoice5S, RenalChoice6S |

- ☐ Subject refuses to continue 'kidney failure' question RenalRefContS

3. Chest pain related to heart disease

Imagine living with **chest pain related to heart disease**:

- You experience chest pain after walking a block or two but can relieve the pain by stopping or taking medicine.
- Your energy level may be low some of the time.
- You can bathe and dress yourself, and feed yourself without difficulty.

Imagine you had the following choice, which would you prefer?

- | | | |
|--|---|------------------------------------|
| <input type="checkbox"/> ___ years living with heart disease | } | ChestPnChoice1S, ChestPnChoice2S , |
| <input type="checkbox"/> ___ years in perfect health | | ChestPnChoice3S, ChestPnChoice4S, |
| <input type="checkbox"/> No preference, because these seem about the same to him/her | | ChestPnChoice5S , ChestPnChoice6S |

- ☐ Subject refuses to continue 'chest pain related to heart disease' question [ChestPnRefContS](#)

4. Stroke

Imagine life after having a **severe stroke**:

- You cannot move the arm or leg on the side that you write with.
- You can stand with a leg brace and walk a short distance with help.
- You can use a wheel chair. You cannot climb stairs.
- You need help to dress, bathe, and use the bathroom. You need help preparing and eating food.
- You might have difficulty speaking or finding the right words.

Imagine you had the following choice, which would you prefer?

- | | | |
|--|---|---|
| <input type="checkbox"/> ___ years living with stroke | } | StrokeChoice1S, StrokeChoice2S, |
| <input type="checkbox"/> ___ years in perfect health | | StrokeChoice4S, StrokeChoice4S, |
| <input type="checkbox"/> No preference, because these seem about the same to him/her | | StrokeChoice5S, StrokeChoice6S |

- ☐ Subject refuses to continue 'severe stroke' question [StrokeRefContS](#)

5. Living without part of your lower leg or foot

Imagine a life after you have lost part of your **lower leg or foot**:

- You may be able to walk with an artificial leg, or you may have to use a wheelchair to get around.
- You might have some difficulty performing daily tasks such as driving, shopping, or cleaning your house.

Imagine you had the following choice, which would you prefer?

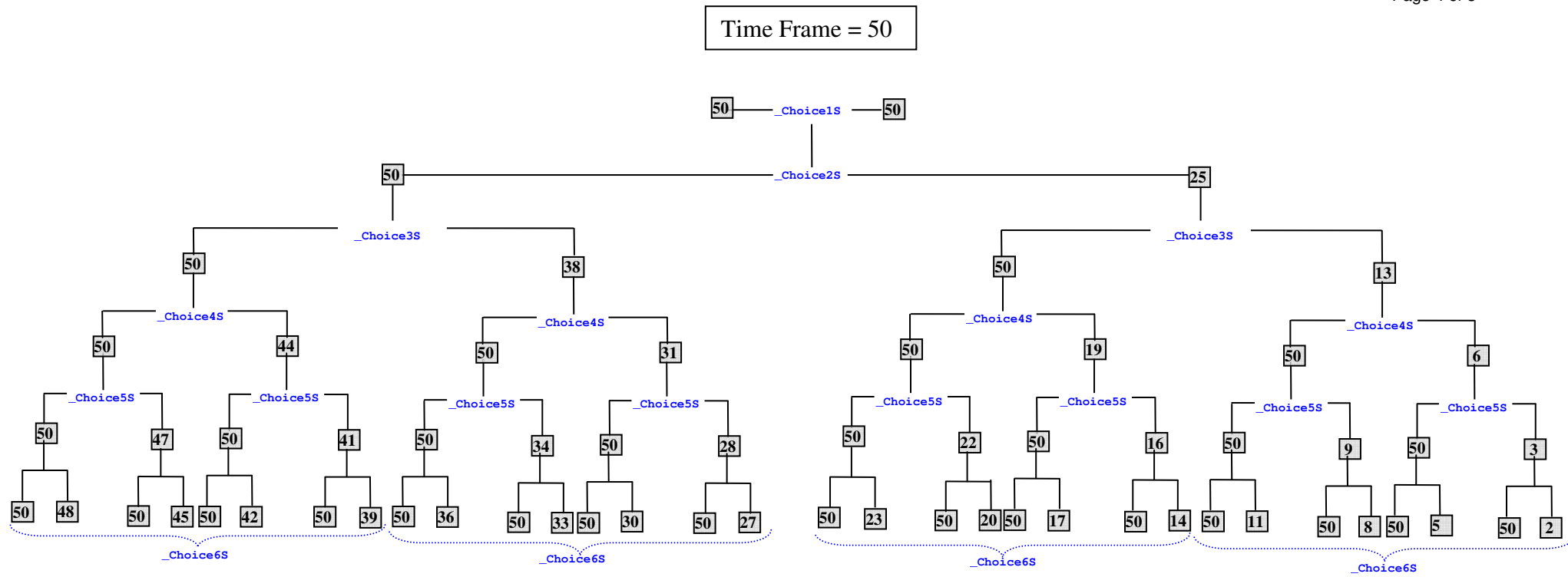
- | | | |
|--|---|---|
| <input type="checkbox"/> ___ years living without part of his/her lower leg or foot | } | LostLegChoice1S, LostLegChoice2S, |
| <input type="checkbox"/> ___ years in perfect health | | LostLegChoice3S, LostLegChoice4S, |
| <input type="checkbox"/> No preference, because these seem about the same to him/her | | LostLegChoice5S, LostLegChoice6S |

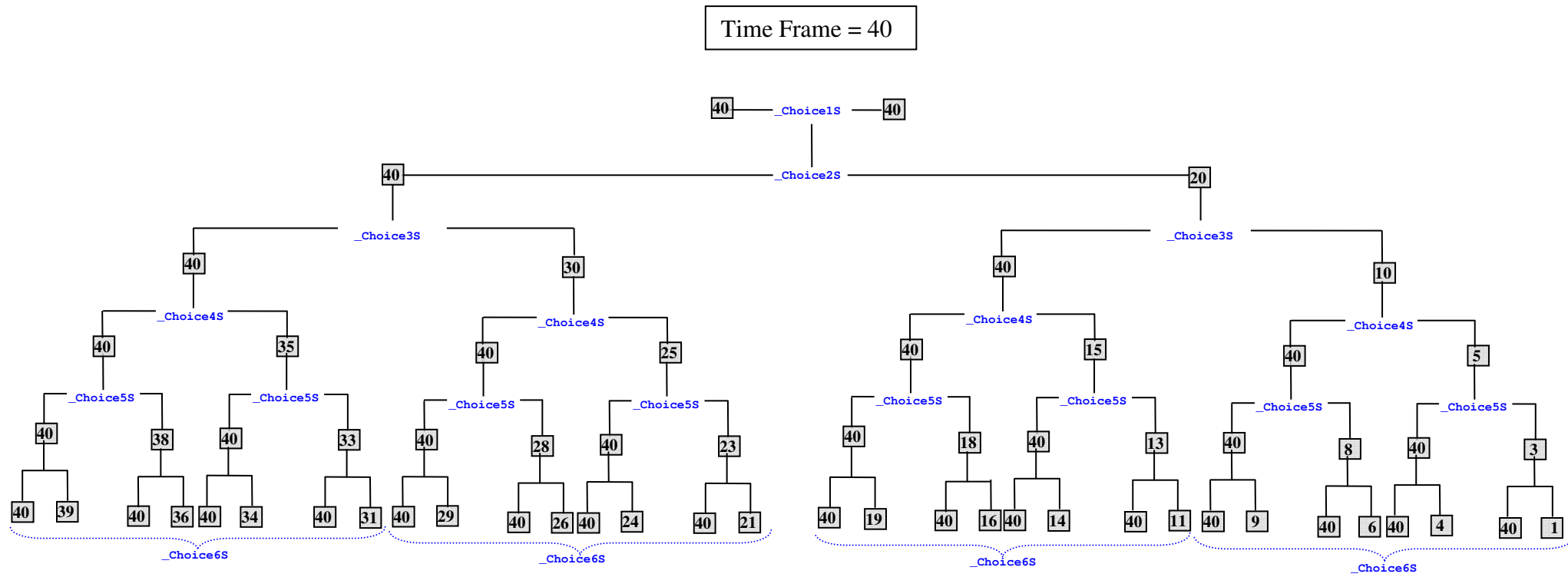
- ☐ Subject refuses to continue 'lost lower leg or foot' question [LostLegRefContS](#)

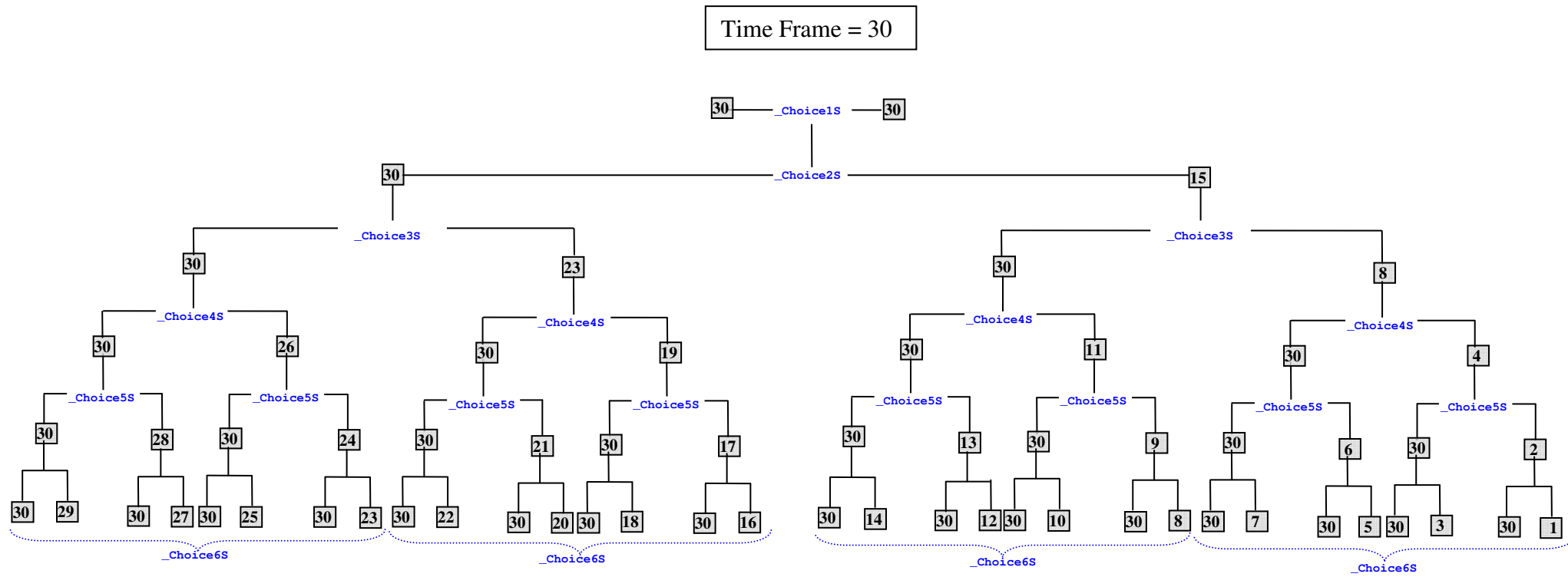
- ☐ Subject refuses to continue survey [RefContS](#)

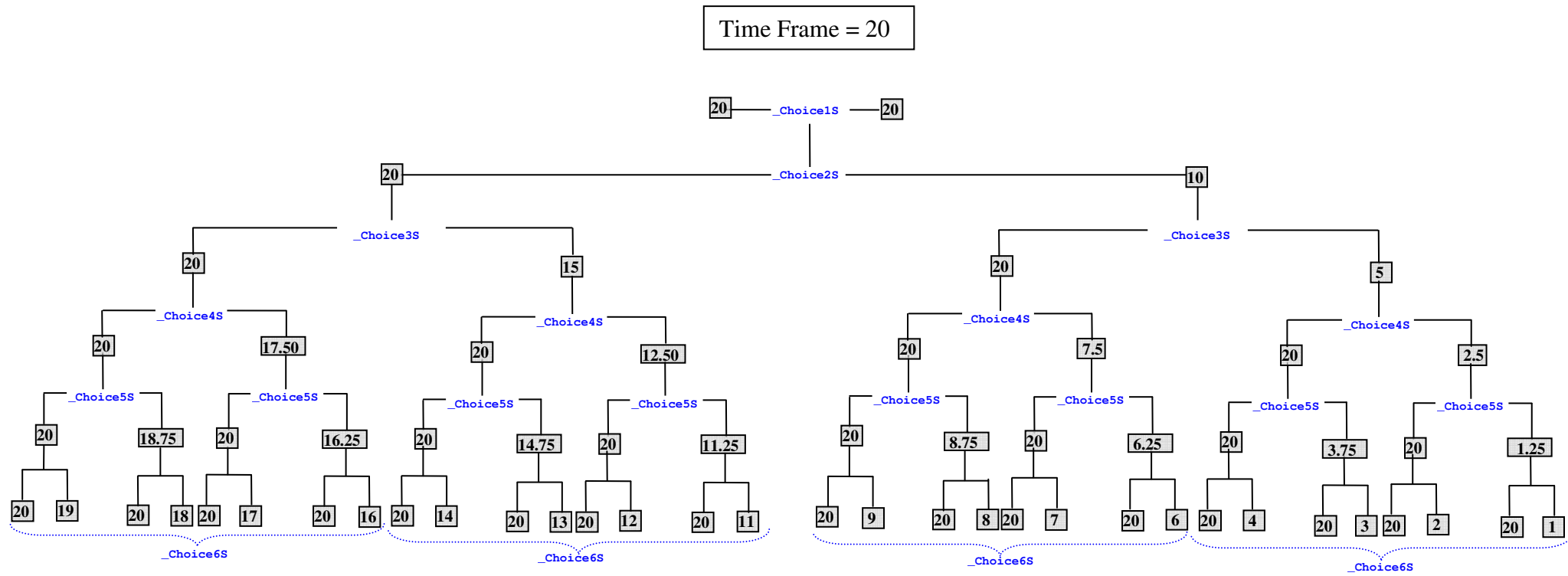
Interviewer: If subject does not choose living in perfect health then discuss answer, determine if subject intends answer and go to next question.

Hierarchical Diagrams









Fictitious example for the Blindness section:

An investigator is asking John this survey. John is a 14 years old boy which puts his “Time Frame” equal to 50. The investigator asks John the following question using the hierarchical diagram flow to plot the number of years for each question.

Question 1: Imagine have the following choice, which would he/she prefer; **50 years living with blindness or 50 years in perfect health?** **_Choice1S**

Answer: **50 years in perfect health**

Question 2: Which would you prefer; **50 years living with blindness or 25 years in perfect health?** **_Choice2S**

Answer: **50 years living with blindness**

Question 3: Which would you prefer; **50 years living with blindness or 38 years in perfect health?** **_Choice3S**

Answer: **38 years in perfect health**

Question 4: Which would you prefer; **50 years living with blindness or 31 years in perfect health?** **_Choice4S**

Answer: **31 years in perfect health**

Question 5: Which would you prefer; **50 years living with blindness or 28 years in perfect health?** **_Choice5S**

Answer: **50 years living with blindness**

Question 6: Which would you prefer; **50 years living with blindness or 30 years in perfect health?** **_Choice6S**

Answer: **30 years in perfect health**

The red boxes represent John’s choices for the Blindness section. Please note that if John had chosen “No Preference” at any point this section would be over.

The same approach must be applied to all sections of this survey (Blindness, Kidney Failure, Chest Pain, Severe Stroke and Living without Part of your Leg).

