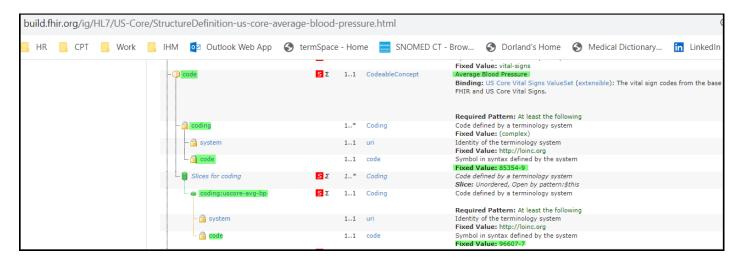
AMA Feedback on US Core Average Blood Pressure profile and other aspects of US Core Vital Signs

Change Request - Should US Core Average Blood Pressure Profile be derived from US Core Blood Pressure Profile?

We suggest that US Core Average Blood Pressure Profile not be derived from US Core Blood Pressure Profile. We do not feel that an Average Blood Pressure is a refinement of a single Blood Pressure measurement.

Additionally, deriving US Core Average Blood Pressure Profile from the US Core Blood Pressure Profile, which already has fixed codes for Observation.code and Observation.component.code, requires slicing coding for Observation.code and Observation.component.code to provide additional fixed codes to further specify the meaning to average blood pressure. While this is allowed per the Profile Specific Implementation Guidance section of the Mandatory and Must Support Data Elements section, it results in US Core Average Blood Pressure Profile having 2 fixed codes for Observation.code and 2 fixed codes for each Observation.component.code. (In contrast, the Vital Signs with Qualifying Elements IG, derives its Average Blood Pressure Profile from the R4 Observation Vital Signs profile rather than from the Vital Signs with Qualifying Elements Blood Pressure Panel Profile.)

Example of Observation.code slicing in the US Core <u>Average Blood Pressure Profile</u> (from "Key elements Tab" in the profile):



Thus, US Core Average Blood Pressure observations will have at least two fixed codings for Observation.code:

- Observation.code.coding.code: 85354-9 Blood pressure panel with all children optional
- Observation.code.coding.code: 96607-7 Blood pressure panel mean systolic and mean diastolic

The US Core Average Blood Pressure example shows the two codes for each element:

```
13.236.1 Example Observation: Average Blood Pressure Example
Page standards status: Informative
Generated Narrative: Observation
 Resource Observation "average-blood-pressure"
Profile: US Core Average Blood Pressure Profile (version 7.0.0-ballot)
category: Vital Signs (Observation Category Codes #vital-signs)
code: Avg Blood pressure systolic and diastolic (LOINCE#96607-7 "Blood pressure panel mean systolic ar
subject: Patient/example: Amy Shaw " SHAW"
effective: 2023-08-03 01:06:52+0000 --> 2023-08-03 13:07:01+0000
performer: Practitioner/practitioner-1 " BONE"
note: Average blood pressure is calculated from 12 measurements taken over 12 hours
   component
   code: Average systolic blood pressure (LOINCE#96608-5 "Systolic blood pressure mean"; LOINC
   value: 109 mm[Hg] (Details: UCUM code mm[Hg] = 'mm[Hg]')
   component
   code: Average diastolic blood pressure (LOINC: #96609-3 "Diastolic blood pressure mean"; LOINC: #8462-4 "Diastolic blood pressure")
   value: 44 mm[Hg] (Details: UCUM code mm[Hg] = 'mm[Hg]')
```

Further specifying Average Blood Pressure by providing additional, more specific codes (as described below for this profile), could result in adding yet a third Observation.code and Observation.component.code.

Profile Specific Implementation Guidance:

- Note that this profile also conforms to the base FHIR Vital Signs Profile 2.
- . The observations MAY have additional codes that translate or map to the Observation code or category codes. For example:
 - o providing a local system specific code
 - o providing more specific codes such as 8306-3 Body height lying in addition to 8302-2 Body height. Several additional observation codes are provided in the FHIR core specification vital signs table [2]. a code system value SHOULD be supplied for each additional code.

Thus, Average Blood Pressure could be further specified as:

24-hour Average Blood Pressure

- Observation.code: 85354-9 Blood pressure panel with all children optional
- Observation.code: 96607-7 Blood pressure panel mean systolic and mean diastolic
- Observation.code: 97844-5 Blood pressure panel 24 hour mean

If Observation.code already has 2 fixed values (as for Ave BP), can the additional code only be more specific than the most specific code, or more specific than either code, or (in some cases) more specific than some combination of both codes? For the example below, can the 2 fixed Average Blood Pressure codes be further refined by adding the code in red which is more specific than the first code but not the second code?

Average Blood Pressure from brachial artery measurements

- Observation.code: 85354-9 Blood pressure panel with all children optional
- Observation.code: 96607-7 Blood pressure panel mean systolic and mean diastolic
- Observation.code: 83389-7 Brachial artery Blood pressure

The approach of multiple codes also adds uncertainty as to how to interpret Observation.code. Sometimes, the more granular code might represent the actual meaning of the observation (as per the IG Ave BP Example 13.236.1 above). At

other times, the meaning of 2 or more codes or component codes might be combined to "post-coordinate" the complete meaning of the observation (e.g., the brachial artery BP example above).

Allowing multiple, roughly semantically equivalent codes from different code systems makes sense when the codes serve different purposes (e.g., ICD for billing, SNOMED for clinical granularity). However, multiple, non-equivalent codes from the same code system for Observation.code could create problems for "SHALL support searching using the combination of the **patient** and **code** search parameters" (below) from Mandatory Search Parameter. It is easier to search for a single code than to attempt to search for a "meaning" that might be post-coordinated multiple ways using more than one code. While the challenge of post-coordinated meaning already exists (e.g., site can be captured in Observation.code, Observation.site, or both), allowing multiple Observation.codes adds to this challenge.

1. GET [base]/Observation?patient=1186747&code=http://loinc.org|8867-4,http://loinc.org|9279-1,http://loinc.org|85354-9

Implementation Notes: Fetches a bundle of all Observation resources for the specified patient and observation code(s). SHOULD support search by multiple codes. The Observation code parameter searches `Observation.code only. (how to search by reference and how to search by token and how to search by token and how to search by token are not search by token and how to search by token are not search by token and how to search by token are not search by token are

Multiple codes also be more complicated for BP and Average BP because the Observation.component.code systolic and Observation.component.code diastolic may need to be refined in the same way as the as Observation.code is refined.

A larger issue (outlined below) is that the approach of fixed Observation.codes for Vital sign profiles contrasts somewhat with other FHIR Observations and Conditions, where a single Observation.code at the appropriate level of granularity can often be selected from a larger bound value set (intensional or extensional). We recognize that evaluating this larger issue is beyond the scope of the Ballot timeline. For this reason, we suggest that, at a minimum, US Core Average Blood Pressure Profile be derived from US Core Vital Sign Profile rather than from US Core Blood Pressure Profile.

Larger issue of fixed values for Vital Sign Profiles:

This section discusses whether an approach should be evaluated that uses value sets for Observation.code and Observation.component.code for profiles derived from Vital Sign Observations (e.g., BP, Temp, etc.). This could potentially allow selection of only one Observation.code to express the needed level of granularity as opposed to the current model which requires a fixed Observation.code for which the meaning can be further refined/qualified with additional Observation.codes, or extensions, or other Observation elements.

Currently, US Core Vital Sign Observation.code has an extensible binding to a very limited value set https://hl7.org/fhir/R4/valueset-observation-vitalsignresult.html#4.4.1.455. (Of note, the sections underlined in red seem to contradict each other.)

4.1.5.2 Extensible

To be conformant, codes in this element SHALL be from the specified value set if any of the codes within the value set can apply to the concept being communicated.

Note that it is the value set binding that is extensible, not the value set itself.

If there is no applicable concept in value set (based on human review), an alternate concept (either system / code pair, or text) may be used instead. The alternate concept can have any level of specificity in an is-a hierarchy (see Condition instance #2).

If there is at least one applicable concept in the extensibly-bound value set with a meaning which includes but is more general than the meaning that is intended to be represented by the element in the resource instance, then the code that is used in the instance SHALL be taken from the value set and should be the closest available match for the intended element instance meaning (i.e. neither more general or more specific). However, a more specific code that more completely represents the intended meaning may also be included in the instance as an additional Coding if the data type is CodeableConcept, but it cannot be used instead of the code from the value set. This helps ensure that systems know which codes they should expect to receive and build logic for and it facilitates interoperability.

The derived profiles (e.g., Blood Pressure, Temperature, each have a fixed Observation.code (from the US Core Vital Sign Profile Observation.code value set), which can then be further refined by adding Observation.codes (as is also done in R4 as described below).

From R4 10.1.30.2 StructureDefinition: BP https://hl7.org/fhir/R4/bp.html:



Currently, Profile Specific Guidance for the <u>US Core Average Blood Pressure profile</u> (and other VS profiles) references additional codes provided in the <u>vital signs table</u> (second image below) which almost seem to be suggesting value sets for Observation.code and Observation.component.code for specific Vital Sign profiles, but outside of an actual value set binding to the profile.

Profile Specific Implementation Guidance:

Note that this profile also conforms to the base FHIR Vital Signs Profile □.

The observations MAY have additional codes that translate or map to the Observation code or category codes. For example:

providing a local system specific code

providing more specific codes such as 8306-3 - Body height - lying in addition to 8302-2 - Body height. Several additional observation codes are provided in the FHIR core specification vital signs table □. a code system value SHOULD be supplied for each additional code.

Excerpt from the vital signs table referenced above.

Body temperature	8310-5	Body temperature - To supplement this vital sign observation, 8327-9 - Body temperature measurement site (oral, forehead, rectal, etc.) and 8326-1 -Type of body temperature device MAY be used as additional observations.	Cel, [degF]	Body Temperature Example
Body height	8302-2	Body height - To supplement this vital sign observation, 8306-3 -Body height - lying (i.e., body length - typically used for infants) MAY be included as an additional observation code.	cm, [in_i]	Body height Example
Head circumference	9843-4	Head Occipital-frontal circumference	cm, [in_i]	Head Circumference Example
Body weight	29463-7	Body weight - To supplement this vital sign observation, 8352-7 - Clothing worn during measure and 8361-8 - Body position with respect to gravity MAY be included as additional observation codes.	g, kg, [lb_av]	Body Weight Example
Body mass index	39156-5	Body mass index (BMI) [Ratio]	kg/m2	Body Mass Example
Blood pressure systolic and diastolic	85354-9	Blood pressure panel with all children optional - This is a component observation. It has no value in Observation.valueQuantity and contains at least one component (systolic and/or diastolic). To supplement this vital sign observation, 8478-0 - Mean blood pressure, 8357-6 - Blood pressure method, 41904-4 - Blood pressure measurement site, 8358-4 - Blood pressure device cuff size, 41901-0 - Type of blood pressure device MAY be used as additional observations.		Blood Pressure Example, Blood Pressure Example with missing Diastolic measurement

This raises the question of whether the Vital Signs Profile Observation.code Value Set could be expanded (e.g., to include Body temperature, Oral temperature, Blood pressure, Brachial artery Blood pressure, etc.) and subsets of the larger Vital Signs value set could then be used for the derived profiles' value sets. Or, whether the Vital Sign Profile could be removed and only the derived profiles (e.g., BP, Body Temperature) are needed with their own Observation.code LOINC Value Sets (required or extensible). (Of note, this last paragraph is merely suggestions and may not work in testing).

2. Comments related to US Core Average Blood Pressure Mandatory and Must Support Data Elements section

In general, it would be nice for all Vital Signs profiles to have guidance and examples that are specific to each profile.

a. Change Request – Add a BP-relevant example (in the Profile Specific Implementation Guidance section)

It would help to include examples that are relevant to the Average Blood Pressure Profile in the in the "Profile Specific Implementation Guidance" section of the Mandatory and Must Support Data Elements section.

Profile Specific Implementation Guidance:

- Note that this profile also conforms to the base FHIR Vital Signs Profile ...
- . The observations MAY have additional codes that translate or map to the Observation code or category codes. For example:
 - · providing a local system specific code
 - providing more specific codes such as 8306-3 Body height lying in addition to 8302-2 Body height. Several additional observation codes are provided in the FHIR core specification vital signs table ... a code system value SHOULD be supplied for each additional code.
- The observation MAY have component observations. For example, to qualify the vital sign observation 8310-5 Body temperature, 8327-9 Body temperature measurement site (oral, forehead, rectal, etc.) may be used as a component observation. Several of these are provided in the FHIR core specification vital signs table ...
- The observation MAY use [extensions] defined by other profiles such as Vital Signs with Qualifying Elements: Average Blood Pressure Profile 2.
- · Information about the protocol or number of measurements used to determine the averages SHOULD be supplied in either:
 - o Observation.note.text (for example, "24-hour ambulatory measurement.")
 - o a component observation in Observation.component
 - an extension
- . Implementers may use this profile as a base for other vital signs in addition to those in this guide.
- · Because the blood pressure values are communicated in the mandatory systolic and diastolic components:
 - o the observation.value[x] element SHOULD be omitted
 - o an Observation without a systolic or diastolic result value, SHALL include a reason why the data is absent in Observation.component.dataAbsentReason
 - all server systems including those that never provide a component observation without a value SHALL support observation.component.dataAbsentReason for the components.

For example, we suggest changing the yellow above, from:

providing more specific codes such as 8306-3 - Body height - lying in addition to 8302-2 - Body height.
 Several additional observation codes are provided in the FHIR core specification vital signs table. a code system value SHOULD be supplied for each additional code.

To something like:

• providing more specific codes such as 97844-5 - Blood pressure panel 24 hour mean in addition to 96607-7 - Blood pressure panel mean systolic and mean diastolic and 85354-9 Blood pressure panel with all children optional. Several additional observation codes are provided in the FHIR core specification vital signs table. A code system value SHOULD be supplied for each additional code. For the Blood Pressure Profile and Average Blood Pressure Profile, if a more specific Observation.code is added to the fixed Observation.code, corresponding Observation.component.code systolic and Observation.component.code diastolic codes SHALL also be added.

EXAMPLE for why the last sentence above was added:

If Observation.code is fixed as in Set 1 below, and an additional, more specific Observation.code is added in Set 2 (in green), then Observation.component.code systolic and Observation.component.code diastolic also need to be refined in the same way in Set 2.

Set 1

- Observation.code: <u>96607-7</u> Blood pressure panel mean systolic and mean diastolic
- Observation.component.code: 96608-5 Systolic blood pressure mean
- Observation.component.code: <u>96609-3</u> Diastolic blood pressure mean

Set 2

- Observation.code: 96607-7 Blood pressure panel mean systolic and mean diastolic
- Observation.code: 97844-5 Blood pressure panel 24 hour mean
- Observation.component.code (systolic): 96608-5 Systolic blood pressure mean
- Observation.component.code (systolic): 8490-5 Systolic blood pressure 24 hour mean
- Observation.component.code (diastolic): <u>96609-3</u> Diastolic blood pressure mean
- Observation.component.code(diastolic): 8472-3 Diastolic blood pressure 24 hour mean

b. Change Request – To example for "qualifying" Components (in Profile Specific Implementation Guidance)

We suggest replacing the Body temperature examples in the yellow highlighted bullet below with appropriate component examples for diastolic and systolic BP.

Profile Specific Implementation Guidance:

- Note that this profile also conforms to the base FHIR Vital Signs Profile ௴.
- . The observations MAY have additional codes that translate or map to the Observation code or category codes. For example:
 - o providing a local system specific code
 - providing more specific codes such as 8306-3 Body height lying in addition to 8302-2 Body height. Several additional observation codes are provided in the FHIR core specification vital signs table . a code system value SHOULD be supplied for each additional code.
- The observation MAY have component observations. For example, to qualify the vital sign observation 8310-5 Body temperature, 8327-9 Body temperature measurement site (oral, forehead, rectal, etc.) may be used as a component observation. Several of these are provided in the FHIR core specification vital signs table ...
- The observation MAY use [extensions] defined by other profiles such as Vital Signs with Qualifying Elements: Average Blood Pressure Profile ...
- · Information about the protocol or number of measurements used to determine the averages SHOULD be supplied in either:
 - o Observation.note.text (for example, "24-hour ambulatory measurement.")
 - o a component observation in Observation.component
 - an extension
- . Implementers may use this profile as a base for other vital signs in addition to those in this guide.
- · Because the blood pressure values are communicated in the mandatory systolic and diastolic components:
 - the Observation.value[x] element SHOULD be omitted
 - o an Observation without a systolic or diastolic result value, SHALL include a reason why the data is absent in observation.component.dataAbsentReason
 - all server systems including those that never provide a component observation without a value SHALL support Observation.component.dataAbsentReason for the components.

Additionally, although the current advice in the yellow bullet above aligns with advice from R4 Observation Vital Signs (in yellow below), we disagree with the component examples provided in yellow above and below. For the BP Profile and Average BP Profile specifically, we feel Observation.component should be used to break Observation.code into its diastolic and systolic BP components, not to further qualify Observation.code.

Body temperature	8310-5	Body temperature - To supplement this vital sign observation, 8327-9 - Body temperature measurement site (oral, forehead, rectal, etc.) and 8326-1 -Type of body temperature device MAY be used as additional observations.	Cel, [degF]	Body Temperature Example
Body height	8302-2	Body height - To supplement this vital sign observation, 8306-3 -Body height - lying (i.e., body length - typically used for infants) MAY be included as an additional observation code.	cm, [in_i]	Body height Example
Head circumference	9843-4	Head Occipital-frontal circumference	cm, [in_i]	Head Circumference Example
Body weight	29463-7	Body weight - To supplement this vital sign observation, 8352-7 - Clothing worn during measure and 8361-8 - Body position with respect to gravity MAY be included as additional observation codes.	g, kg, [lb_av]	Body Weight Example
Body mass index	39156-5	Body mass index (BMI) [Ratio]	kg/m2	Body Mass Example
Blood pressure systolic and diastolic	85354-9	8lood pressure panel with all children optional - This is a component observation. It has no value in Observation.valueQuantity and contains at least one component (systolic and/or diastolic). To supplement this vital sign observation, 8478-0 - Mean blood pressure, 8357-6 - Blood pressure method, 41904-4 - Blood pressure measurement site, 8358-4 - Blood pressure device cuff size, 41901-0 - Type of blood pressure device MAY be used as additional observations.		Blood Pressure Example, Blood Pressure Example with missing Diastolic measurement

Additionally, in general, we do not feel that Observation.component should qualify/refine Observation.code in a way that overlaps with information that can be captured by a profile Element (i.e., Observation.site). For example, rather than using Observation.component to further specify the body site (as suggested in all the yellow sections of the two images above), Observation.bodySite (e.g., oral cavity, forehead, rectum) should be used. The same is true for the above

suggestion to use 8357-6 - Blood pressure method as a component observation. Instead, Observation.method should be used to specify the method.

Multiple options to represent the same meaning may impact interoperability and should be avoided if possible.

Example: Options to represent "Oral temperature" in the US Core IG appear to include:

Option 1 – Using Observation.site

Observation.code: 8310-5 - Body temperature

Observation.site: 74262004 | Oral cavity structure (body structure) |

Option 2 - Using Component

• Observation.code: 8310-5 - Body temperature

AND

- Observation.component.code: 8327-9 Body temperature measurement site
 - Observation.component.value: 74262004 | Oral cavity structure (body structure) |

Option 3 – Refining the fixed value for Observation.code (in the Body temperature profile)

Observation.code: 8310-5 - Body temperature (fixed value)
 AND

Observation.code: 8331-1 Oral temperature

c. Change request - To capturing the number of measurements in an Average BP

For the bullet in yellow below from "Profile Specific Implementation Guidance", we disagree with the advice that the number of measurements contributing to an Average blood Pressure can be provided using Observation.component, Observation.note, or an extension.

Profile Specific Implementation Guidance:

- Note that this profile also conforms to the base FHIR Vital Signs Profile ☑.
- The observations MAY have additional codes that translate or map to the Observation code or category codes. For example:
 - o providing a local system specific code
 - providing more specific codes such as 8306-3 Body height lying in addition to 8302-2 Body height. Several additional observation codes are provided in the FHIR core specification vital signs table . a code system value SHOULD be supplied for each additional code.
- The observation MAY have component observations. For example, to qualify the vital sign observation 8310-5 Body temperature, 8327-9 Body temperature measurement site (oral, forehead, rectal, etc.) may be used as a component observation. Several of these are provided in the FHIR core specification vital signs table of the c
- The observation MAY use [extensions] defined by other profiles such as Vital Signs with Qualifying Elements: Average Blood Pressure Profile ...
- Information about the protocol or number of measurements used to determine the averages SHOULD be supplied in either:
 - o Observation.note.text (for example, "24-hour ambulatory measurement.")
 - a component observation in Observation.component
 - o an extension
- Implementers may use this profile as a base for other vital signs in addition to those in this guide.
- · Because the blood pressure values are communicated in the mandatory systolic and diastolic components:
 - the Observation.value[x] element SHOULD be omitted
 - o an Observation without a systolic or diastolic result value, SHALL include a reason why the data is absent in Observation.component.dataAbsentReason
 - all server systems including those that never provide a component observation without a value SHALL support Observation.component.dataAbsentReason for the components.

The number of BP readings that contribute to an Average BP is critical to interpreting the importance of the average and we feel this should be handled consistently using an Extension. Observation.notes are not even Must Support.

The team building the CardX Hypertension Management IG has decided to handle this with a mandatory "Number of Measurements" Extension. We advise the same for US Core.

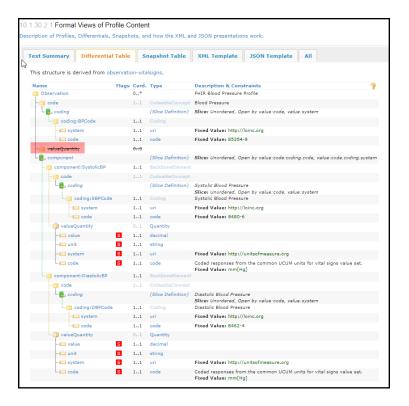
d. Change Request - Prohibit Observation.value[x] for the BP and Average BP Profiles

We feel that Observation.value should be prohibited the US Core Average Blood Pressure profile and US Core Blood Pressure profile. Then, the bullet highlighted in yellow below (from Profile Specific Implementation Guidance) could be removed. (Observation.value is prohibited in **Vital Signs with Qualifying Elements** 1.0.0 – STU 1 US <u>Blood Pressure</u> Panel profile).

Profile Specific Implementation Guidance: . Note that this profile also conforms to the base FHIR Vital Signs Profile ₫. . The observations MAY have additional codes that translate or map to the Observation code or category codes. For example: o providing a local system specific code o providing more specific codes such as 8306-3 - Body height - lying in addition to 8302-2 - Body height. Several additional observation codes are provided in the FHIR core specification vital signs table . a code system value SHOULD be supplied for each additional code. • The observation MAY have component of observations. For example, to qualify the vital sign observation 8310-5 - Body temperature, 8327-9 - Body temperature measurement site (oral, forehead, rectal, etc.) may be used as a component observation. Several of these are provided in the FHIR core specification vital signs table 2. • The observation MAY use [extensions] defined by other profiles such as Vital Signs with Qualifying Elements: Average Blood Pressure Profile ... Information about the protocol or number of measurements used to determine the averages SHOULD be supplied in either: o Observation.note.text (for example, "24-hour ambulatory measurement.") o a component observation in Observation.component · Implementers may use this profile as a base for other vital signs in addition to those in this guide. · Because the blood pressure values are communicated in the mandatory systolic and diastolic components: o the observation.value[x] element SHOULD be omitted an Observation without a systolic or diastolic result value. SHALL include a reason why the data is absent in Observation.component.dataAbsentReason all server systems - including those that never provide a component observation without a value - SHALL support observation.component.dataAbsentReason for the

NEW since 20231206: Of note R4 BP prohibits Observation.value

components.



The current options below for Observation.derivedFrom should be reduced to only the BP profile:

- 🗗 derivedFrom	Σ	0*	Reference(DocumentReference	Related measurements the observation is made from
			ImagingStudy Media	
			QuestionnaireResponse	
			MolecularSequence Vital Signs	
			Profile)	

All other Vital Signs profiles may also need to be looked at for constraining allowed references for Observation.derivedFrom and Observation.member



3. Technical corrections

- a. In the first paragraph under https://build.fhir.org/ig/HL7/US-Core/StructureDefinition-us-core-average-blood-pressure.html#root), it states, "It is based on the US Core Average Blood Pressure Profile ...".
 Since the profile is currently derived from of US Core Blood Pressure Profile, this should be changed to "It is based on US Core Blood Pressure Profile...".
- b. Section 4.1.16 https://build.fhir.org/ig/HL7/US-Core/profiles-and-extensions.html#observation

Remove the first two rows in green below and place US Core Average Blood Pressure Profile in the US Core Vital Signs Profile section. US Core Blood Pressure Profile is already in the US Core Vital Signs Profile section.

