



A proof of concept for using probabilistic methods to simulate a virtual clinical trial to assess the clinical effectiveness of experimentally tested interventions.

## INTRODUCTION

Accounting for 7% of all fall-related injuries and over 30% of fall-related hospitalizations<sup>1</sup>, **hip fractures** are a serious health concern for older adults. Costing an estimated 1.1 billion annually<sup>2</sup>, ~25% of cases result in death within the first year of injury<sup>3</sup>.

Previous experimental studies have shown the biomechanical effectiveness of interventions<sup>4,5</sup>. Logistical and cost barriers have prevented the clinical effectiveness of certain interventions from being quantified.

The objective of this study was to use a **mechanistic, probabilistic model** of impact dynamics to predict the **clinical effectiveness** of **safety flooring** and **hip protectors** at reducing hip fracture risk.

## METHODS

### Probabilistic Model

#### Generating a Virtual Sample

A sample of 100 000 virtual individuals (VI) were generated to be representative of the older adult population in terms of physical characteristics (Height, Mass, Age, Sex).

This was done by defining the Canadian population probability distributions for each physical characteristic (example: Figure 1).

VIs were defined by drawing values pseudo-randomly along each defined distribution.

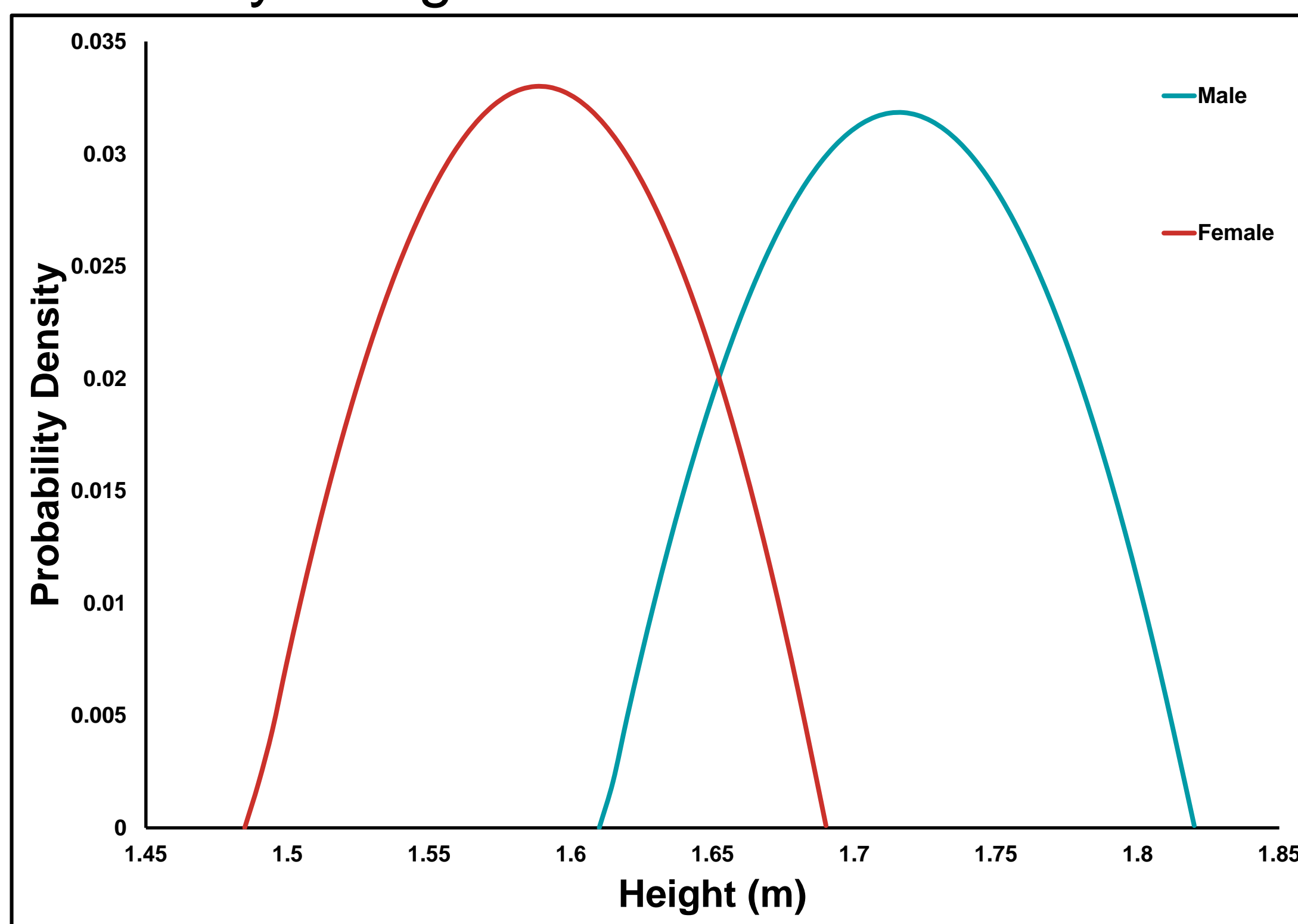


Figure 1: Height Probability Distributions for Older Adults

### Mechanistic Model

Factor of Risk (FOR) principles were used to assess hip fracture risk, where:

**FOR = Impact Force / Bone Strength**  
**When FOR > 1, Fracture Expected**

Impact force and bone strength were calculated by using the physical characteristics of the VI in conjunction with previously defined equations<sup>6-8</sup>.

## METHODS

### Experimental Data

#### Developing Regression Equations

Data from studies investigating the effects of a hip protector (**HipSaver, Figure 2A**) and a safety floor (**SmartCells, Figure 2B**) on impact force during simulated lateral impacts (using human volunteers and a mechanical test system, respectively) was used to develop **impact force attenuation regression equations** based on the characteristics of the volunteers and the mechanical test system.

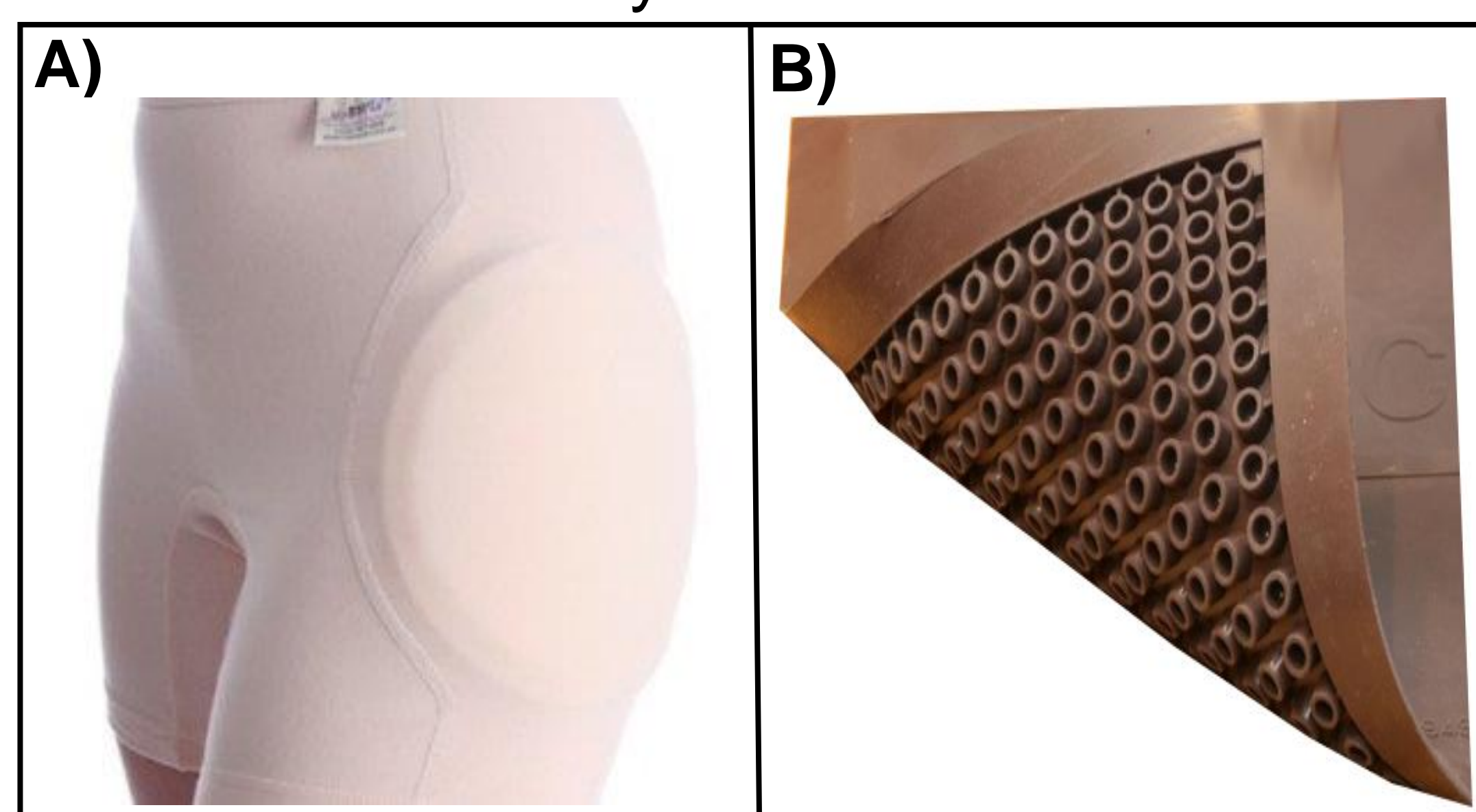


Figure 2: Previously Tested Interventions;  
A) HipSaver Protector, B) SmartCells Safety Floor

These regression equations were used to calculate the force attenuation provided by the interventions for each VI; this was used to calculate a second, “intervened”, Factor of Risk. Completed model seen in Figure 3.

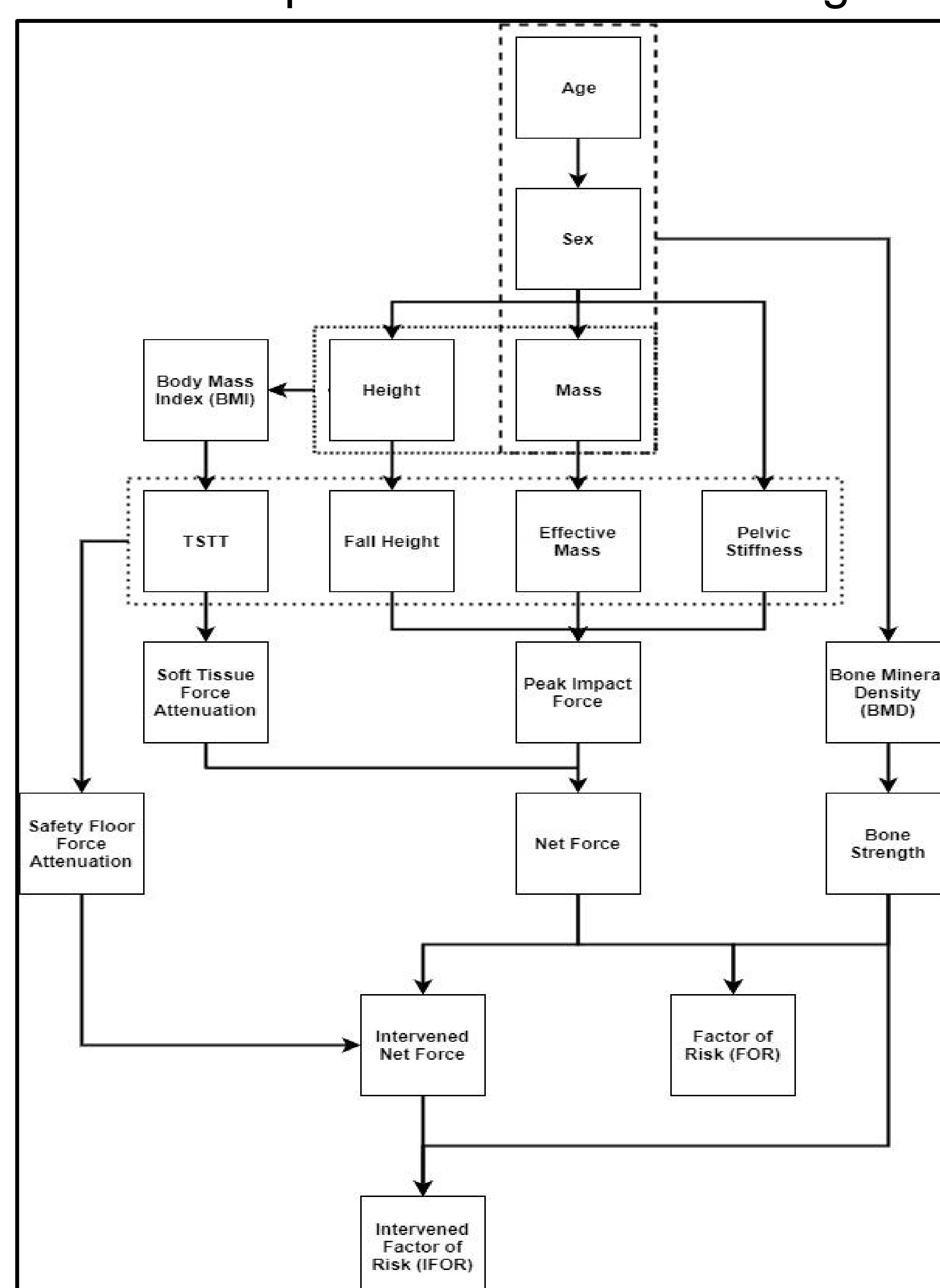


Figure 3: Probabilistic Model Structure and Data Flow

### Computing Clinical Effectiveness

Clinical effectiveness of the interventions was quantified by comparing the number of expected fractures at baseline (no intervention) to the number of fractures expected with either intervention.

## RESULTS

- Simulations predict substantial reduction in hip fracture risk (Figure 4, Tables 1&2)

### Factor of Risk (FOR) Distributions

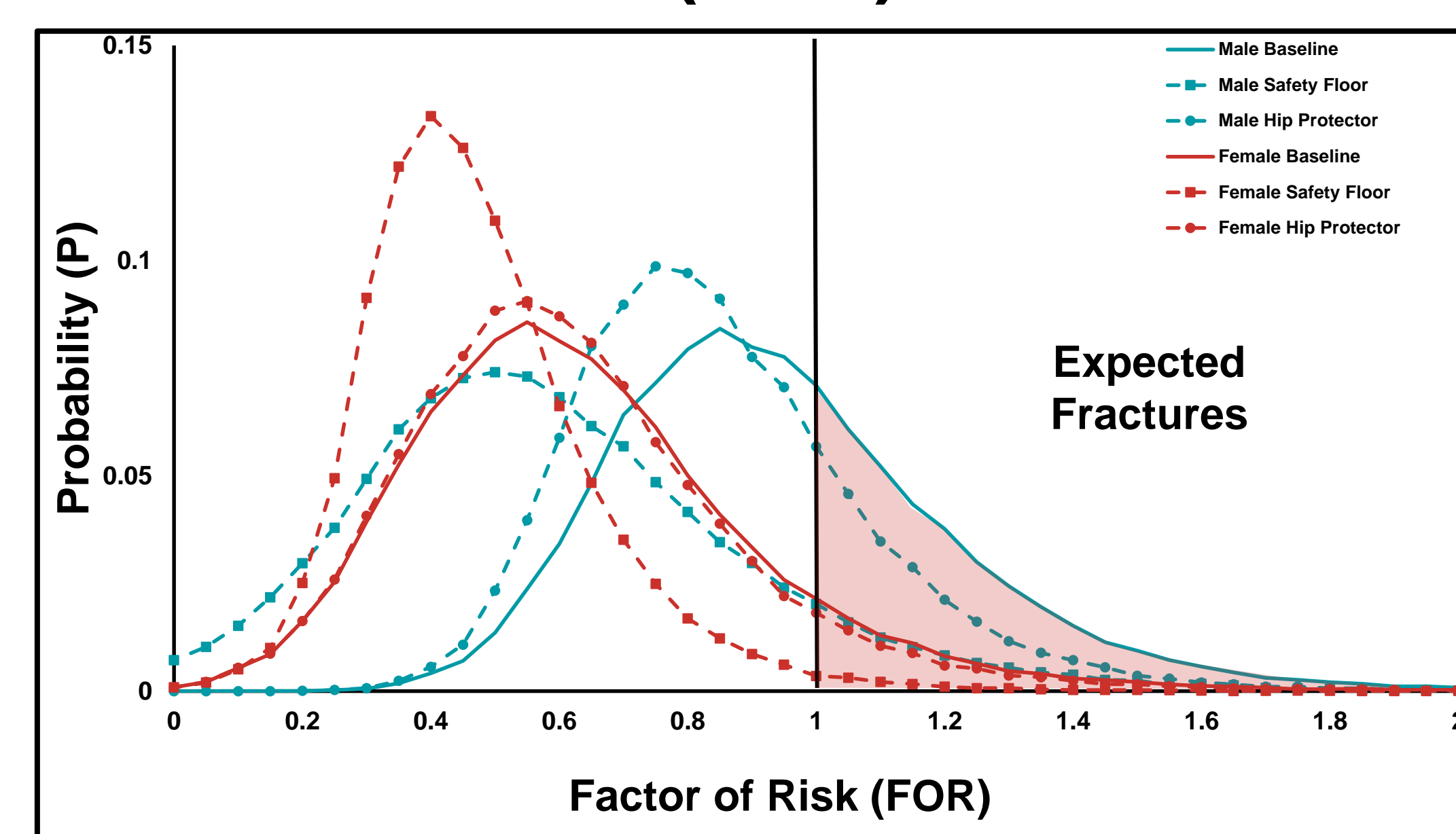


Figure 4: Comparison of Probability Density Functions for FOR by Sex and Intervention; Shaded Area Represents Proportion of Expected Fracture Cases

Table 1: Mean (SD) Factor of Risk for the Baseline, Hip Protector, and Safety Floor Conditions

	Baseline FOR	Hip Protector FOR	Safety Floor FOR
Female mean (SD)	0.61 (0.28)	0.59 (0.27)	0.45 (0.19)
Reduction from Baseline (%)		3.30%	26.20%
Male mean (SD)	0.93 (0.28)	0.83 (0.23)	0.56 (0.31)
Reduction from Baseline (%)		10.60%	39.80%

Table 2: Number of Expected Hip Fractures for the Baseline, Hip Protector, and Safety Floor Conditions

	Baseline	Hip Protector	Safety Floor
Female # FX (% total)	4312 (8.1%)	3414 (6.4%)	617 (1.2%)
Reduction from Baseline (%)		20.8%	85.7%
Male # FX (% total)	15870 (33.8%)	9066 (19.3%)	3801 (8.1%)
Reduction from Baseline (%)		42.9%	76.0%

## DISCUSSION

- Proof of concept for performing “virtual” clinical trial to predict clinical effectiveness of experimentally tested interventions
- The model predicted a >20% reduction in the expected number of hip fracture cases with the use of these interventions; decreased risk of fracture
- Predicted clinical effectiveness of these interventions need to be validated against clinical trial data
  - 4 year safety flooring clinical trial soon to be completed

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## ACKNOWLEDGEMENTS

