



# STRATEGIC ROADMAP TO PREVENT SECONDARY FRACTURES

Final Version

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BETTER DECISIONS.  
**BETTER HEALTH.**

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## **SUMMARY OF ELEMENTS OF STRATEGIC ROADMAP**

- 1. Strengthen working relationships with patient advocacy organizations and primary care clinician groups.**
  - a. Building further trust with these stakeholder groups will be essential to have the required support to successfully implement all other elements of the Strategic Roadmap.***
  - b. A key near-term deliverable would be a more detailed and specific Action Plan, to be developed in partnership with willing groups, and guiding implementation of key elements of this Strategic Roadmap. As part of the development of the Action Plan, we will identify those groups and individuals who are willing to continue to participate in a voluntary coalition to implement the selected activities.***
- 2. Clarify the target population for focus of efforts over next two to three years.**
  - a. We recommend that the target population should be patients at or over the age of 65 years with a hip fracture or vertebral fracture that comes to clinical attention or is incidentally detected. This choice is well supported by existing data on fractures, risk level, and clinical consensus.***
  - b. Other high-risk patient populations would be the focus of a later phase of this work, or be addressed by other programs and initiatives, with which this work will be coordinated.***
  - c. Because of public concerns about the potential harms of drug treatment (including atypical femur fractures and ONJ), it will be important to provide accurate information on these risks and on strategies that may reduce these risks, as well as on the risks of not being treated.***
- 3. Decide on specific measurable goals to achieve with the target population and define efficient mechanisms to track progress toward these goals.**
- 4. Collect and analyze lessons learned from selected past programs and initiatives.**
  - a. Drawing on published reports, expert input, etc. – determine what programs and approaches have worked well, which have not worked, and the most likely explanations for success or lack thereof.***
  - b. Be very cautious about repeating modest variations of programs that have failed.***
- 5. Evaluate and prioritize activities designed to achieve the goals defined above.**
  - a. Agree on a core set (5-7) of meaningful process and outcome measures to evaluate quality of care in the target patient population.***
  - b. Meet with CMS to explore potential mechanisms to pay for case management programs and/or apply value-based payment incentives to care of these patients.***
  - c. Review existing clinical guidelines from primary care and specialty organizations to determine whether the high priority target population and proposed interventions***

*are consistent with them. Based on the advice in this Roadmap and the review of clinical guidelines, develop a short, simple, clinical recommendation for the target population. Disseminate the recommendation in trusted and prominent publications.*

- d. Work with patient, primary care, and specialist partners to support broad circulation of the short, simple, clinical recommendation as well as the Action Plan (mentioned in #1 above) to their respective members / constituents.*
  - e. Develop and circulate educational material for patients, primary care clinicians, and specialists that highlight clinical recommendations that are aligned with project goals.*
- 6. Consider partnerships with integrated health care delivery systems to develop system-specific programs targeted to prevent second fractures.**
- a. Ideally focus on those with, for example, low rates of drug treatment and case management use, or other measures consistent with those identified in Recommendation 3.*
  - b. Pilot studies may allow for refinement of target population, interventions, collection of process and outcomes data.*
- 7. Align separate PR / media activities (such as NBHA, NIAMS, others) with core elements of this Strategic Roadmap**

## INTRODUCTION

Older people who have suffered a hip or vertebral fracture are at extremely high risk of another fracture, yet a majority of them do not receive recommended treatments following their fracture. As a result, this group remains at high risk of second fractures despite the availability of interventions that are known to reduce this risk. Several large delivery systems in the US have made substantial progress toward improved care, and many people in this group are treated appropriately in the UK and in other countries because of focused efforts to align clinical practice with current evidence.

This situation is analogous to the inadequate care provided to patients who were hospitalized for a heart attack prior to the year 2000, many of whom were discharged from the hospital without being offered treatment with beta-blockers, aspirin, and cholesterol lowering drugs – all of which were known to reduce the chance of another heart attack. Focused attention to this problem over several years resulted in more than 90% of these people receiving these treatments.

We believe that the many organizations working on issues around osteoporosis and bone health can find common ground to agree on a pathway for focused attention to reduce the number of avoidable second fractures. The American Society for Bone and Mineral Research (“ASBMR”) is committed to working with a coalition of experts and stakeholders to achieve this goal. The following Strategic Roadmap draws heavily upon discussions during an ASBMR-supported multi-stakeholder meeting held in Crystal City, Virginia on July 19, 2017. This meeting was organized and convened by the Center for Medical Technology Policy (“CMTP”), an independent non-profit dedicated to evidence-based policy. Through a process of analysis and deliberation, we have identified a series of activities intended to reduce the incidence of second fractures, through the collaboration of ASBMR with other organizations and individuals.

CMTP provided a draft of this Strategic Roadmap to various experts and stakeholders, including all those who had attended the July meeting as well as additional parties. All comments received by CMTP or ASBMR were reviewed and considered. The comments and potential amendments of the Roadmap also were discussed with an expert advisory group.

**This Strategic Roadmap was prepared by CMTP for ASBMR and reflects its analysis and recommendations.** The recommendations are recapped and prioritized in the last section of the Roadmap. ASBMR will continue to work with all willing partners, including patient and consumer groups, primary care clinicians, and other interested experts and stakeholders, to reach consensus on specific activities that are most likely to decrease the number of preventable second fractures. While this Roadmap is applicable to a treatment gap that exists globally, many of the recommended actions are designed for implementation in the US, although several may have relevance to improving care outside the US. The proposed actions are intended to complement other efforts to improve bone health, most of which were discussed during the stakeholder meeting or in the context of subsequent discussions.

## ELEMENTS OF STRATEGIC ROADMAP

### 1. STRENGTHEN WORKING RELATIONSHIPS WITH PATIENT ADVOCACY ORGANIZATIONS AND PRIMARY CARE CLINICIAN GROUPS.

- a. Building further trust with these stakeholder groups will be essential to have the required support to successfully implement all other elements of the Strategic Roadmap.*
- b. A key near-term deliverable would be a more detailed and specific Action Plan, to be developed in partnership with willing groups, and guiding implementation of key elements of this Strategic Roadmap. As part of the development of the Action Plan, we will identify those groups and individuals who are willing to continue to participate in a voluntary coalition to implement the selected activities.*

In any public health initiative, the patients whose care is at issue and the clinicians who guide patient care are key partners. The active involvement of these groups in developing and implementing this initiative will increase the likelihood of success. Their ambivalence or skepticism toward an initiative will form a significant barrier. Given the recent history of osteoporosis treatment, which has been in part characterized by skepticism towards the motivations and recommendations of experts, care will need to be taken to build collaborative, respectful, and trust-based partnerships. **To this end, decision-making and actions associated with each of the strategic steps described below should entail partnership with patient and primary care clinician groups.** This emphasis is not to imply that these will be the only stakeholders or collaborators who may or should participate. These groups, however, have been historically under-represented in prior efforts and should be a focus of engagement to ensure their priorities and values are clearly reflected, and to build constructive relationships for implementing the Roadmap successfully.

Many types of health care professionals, of course, either actually do or potentially could interact with people who have experienced a fracture. Orthopedic surgeons, for example, are often the first physicians to treat patients with hip fractures and have recognized the important role they can hold in secondary fracture prevention with programs such as the American Orthopaedic Association's "Own the Bone."<sup>1</sup> Several types of therapists also work with hip fracture patients during and after their hospitalization; radiologists may incidentally diagnose vertebral fractures; dentists/oral surgeons and pharmacists may counsel patients on medications to treat osteoporosis. **Partners thus would ideally include patients and patient advocates, consumer groups, orthopedic surgeons, occupational therapists, physical therapists, rehabilitation therapists, nurse practitioners, physician assistants, family practitioners, general internists, dentists, radiologists and radiologic technicians, clinical pharmacists, and gynecologists, among others.**

**A first step in this partnership is the development of a specific and detailed Action Plan, based on this Strategic Roadmap and crafted with substantive participation of these groups. As described in more detail throughout the rest of the Roadmap, the development process should include input on the initiative's target population, goals, and measures of progress.** The recommendations contained in this Roadmap will be translated into the specific actions that will need to be taken in order to achieve them. Actions will be accompanied by timelines, leaders and responsible parties, resources available, etc. Memoranda of understanding may be useful to document any commitments that various organizations

make, whether to lead accomplishment of an action, provide resources, or simply to inform others of planned activities such as public awareness campaigns.

As the Action Plan is developed and completed, a coalition of interested volunteers will be identified who are willing to serve as “champions” to help implement the strategic plan. These patient and primary care volunteers would be asked to speak and educate on the initiative, provide input on compelling messaging for the communities they represent, and provide insight on the best ways to reach patients and primary care clinicians to effect change. They could also help to broaden the network of champions; for example, an occupational therapist may be able to leverage contacts in a national professional organization to identify colleagues in localities across the nation willing to disseminate information.

In addition to patient and primary care group volunteers, and the participation of other stakeholders, it would clearly be beneficial to identify other parallel and allied initiatives and look for ways to collaborate and leverage available resources. In considering these opportunities for partnering, care will be taken to consider the sources of funding associated with related projects. For some stakeholders, industry funding is perceived as suspect. For these observers, some health care providers are seen as “captured” by industry, or viewed as putting their own financial interests ahead of those of their patients. **While it may be difficult to achieve, to avoid these pejorative perceptions, this initiative would ideally be supported primarily by funding sources other than life science companies, while ensuring that the expertise from this sector is maintained.** Non-industry sources of funding, such as the Robert Wood Johnson Foundation, will be explored and considered. Care will also be taken to manage potential conflicts of interest that might arise from close association with parallel initiatives that do receive industry support. In all such matters, full transparency must be encouraged. This approach should help to build trust-based relationships with patient and primary care practice groups.

## **2. CLARIFY THE TARGET POPULATION FOR FOCUS OF EFFORTS OVER NEXT TWO TO THREE YEARS.**

- a. We recommend that the target population should be patients at or over the age of 65 years with a hip fracture or vertebral fracture that comes to clinical attention or is incidentally detected. This choice is well supported by existing data on fractures, risk level, and clinical consensus.*
- b. Other high-risk patient populations would be the focus of a later phase of this work, or be addressed by other programs and initiatives, with which this work will be coordinated.*
- c. Because of public concerns about the potential harms of drug treatment (including atypical femur fractures and ONJ), it will be important to provide accurate information on these risks and on strategies that may reduce these risks, as well as on the risks of not being treated.*

**We believe that the likelihood of achieving significant changes in care will be maximized if the population targeted for intervention is narrowly defined.** Existing clinical guidelines for fracture prevention are varied and sometimes contradictory, particularly in areas where evidence is limited. Agreement on a well-defined patient population for which evidence is strongest will make it easier to reach consensus on the steps necessary to improve care for these patients. By increasing the probability of achieving broad stakeholder support, this approach also will increase available resources (the more

stakeholders involved and supporting the project, the more the potential resources that can be secured, provided, or leveraged). The history of prior initiatives also argues for a focused approach. Broadly framed efforts are more likely to be viewed warily by some stakeholders and may provoke controversy that could slow progress in both patient and clinician groups for which immediate action is needed. The need for a carefully circumscribed effort also leads to advice to focus current energy on achieving improvement in the US. Just as international ideas and experiences will inform all the steps of this project, we hope that the ideas and results from this project will inform international efforts in the future. Expanding this initiative to include goals to achieve internationally, however, would create significant challenges to its success and jeopardize potential accomplishments.

**The population to target for intervention should be at substantially increased risk of fracture, potential interventions should have been shown to be effective at reducing that risk, and a significant treatment gap should be easily demonstrable.** Ideally, for purposes of implementation, the criteria used to identify the target population should be simple and precisely defined. The more complicated the criteria, the more difficult implementation will be. The target population preferably would also be readily identifiable in the sense that resources expended on case finding activities should be minimized.

**“Patients  $\geq 65$  years old who have suffered a hip fracture or a vertebral fracture that comes to clinical attention or is incidentally detected” is a population that meets these criteria and for which we believe a multi-stakeholder consensus could be achieved.** To begin with, the population is simply defined and traditional “case finding” is not necessary because people are already identified and in the process of obtaining care. It also has been recognized for some time that people who have experienced one osteoporotic fracture are at significantly higher risk of a subsequent fracture,<sup>2</sup> and the risk appears to be particularly high in older women during the first year following the index fracture (greater than five times the risk).<sup>3</sup> Approximately 25% of older men and women who have a hip fracture will have a second fracture within one year, as will around 20% of older patients who have a vertebral fracture.<sup>2</sup> The clinical presentation is sufficient to diagnose osteoporosis and to begin evaluating the patient for secondary causes and for treatment. Bone mineral density testing at this point may be useful for establishing a baseline for monitoring patients or for other purposes, but is not required in order to identify the target population and to diagnose osteoporosis.

The second criterion – that effective interventions should be available – is also met: several systematic reviews, for example, have concluded that bisphosphonates reduce the risk of vertebral fractures in numerous populations as well as the risk of hip and non-vertebral fractures in patients who have already experienced a fracture.<sup>4–9</sup> Other effective pharmacologic therapies, including anabolic drugs, are also available. In terms of non-pharmacologic interventions, the Centers for Disease Control and Prevention have assembled a compendium of interventions that have been shown to reduce falls in older adults,<sup>10</sup> to provide one example. Finally, a variety of studies have shown that people with hip and vertebral fractures are not receiving appropriate diagnosis and treatment (ranging from 8.3% to 30%).<sup>11,12</sup>

Although we believe that the evidence supporting this target population is quite substantial, it will be necessary to collect the relevant published peer-reviewed studies and other data in order to be able to demonstrate its strength to stakeholders. The evidence compilation will need to be impartial and transparent, acknowledging any areas that are not as strongly supported, and including any contrary evidence. At the same time, the purpose for which the target group is being chosen -- to help primary care clinicians identify patients who need to be assessed for treatment – must be kept in mind. Good clinical judgment indicates that potential causes of any fracture in an elderly person must be assessed and potential interventions considered. In this clinical context, the evidence does not need to be



absolute – definitive randomized double-blind multi-center international trials are not needed for every subgroup of the target population. For example, the evidentiary foundation for men is not as robust as it is for women: there simply are not as many studies. Nevertheless, the available evidence supports the idea that medication is effective at preventing fractures in men and there is no particular *a priori* reason to think it would not be. An additional patient safeguard exists because health care decision making today is shared and primary care clinicians and patients will be discussing evaluation and next steps together. If there are subgroups within the target population for which some evidence needs to be reasonably extrapolated, clinicians should explain the data limitations to their patients and talk through any concerns.

The compilation of evidence should address some further issues as well. For example, collecting comparative data on other potential populations at increased risk will help address any issues raised by proponents of focusing on broader populations. Even more importantly, because concern about possible adverse events associated with pharmacological treatment has been a substantial barrier to treatment, appropriate and accurate information about the relative risks of treatment versus non-treatment should be assembled. Additionally, a number of actions have been proposed to reduce the risk of adverse events, particularly atypical femoral fractures and osteonecrosis of the jaw, including limiting duration of use of medications, optimizing the timing of invasive dental surgery, attempting to identify prodromal symptoms, and monitoring patients. Clinicians need easy access to reliable and up-to-date data on the efficacy of such actions. Not only do data on these issues need to be assembled, but educational materials for patients communicating the data should be drafted using the expertise of specialists in risk communication, and then tested with patients to determine how well the materials convey the necessary information.

A consensus among stakeholders at the summit in support of a similar target population was nearly reached and we believe, based on comments received on the draft Roadmap as well as recent discussions, that a consensus can be achieved for this target population. One relevant issue discussed at length both at the summit and in the following review period involved whether 50 years or 65 years should be the lower age for defining the population. We have recommended 65 years and older for a number of reasons: 1) most of the fractures occurring in the 50 years and older population, especially hip fractures, occur in the 65 years and older population; 2) the evidence base is more developed for older patients; 3) gaining the trust of primary care clinicians and patients will be easier with a more narrowly defined and more strongly supported target population; 4) patients 65 years and older are covered primarily by a single program in the US: Medicare; 5) health care data on this population are more readily available than for most other groups; and 6) the age of 65 seems to be more intuitively obvious to stakeholders.

Setting the initial cutoff at 65 years does *not* mean that people between the ages of 50 and 65 who experience a hip or vertebral fracture should not be evaluated. **In defining the target population and implementing the proposed activities, it is recognized that fracture prevention is also needed for other high-risk populations.** Several stakeholders at the July summit expressed concerns about the possibility of causing misunderstanding about what the importance of the target population is and inadvertently compromising other fracture prevention efforts. Once we have seen progress with the activities focused on the highest risk patients, it should be possible to expand the program to additional people at high risk of fracture. A network of involved stakeholders will have been established, primary care clinicians and specialists will have increased trust in one another, and people at risk of fracture will have increased confidence in their primary care practitioners. These factors will provide a solid foundation for future efforts targeted at broader populations.

### 3. DECIDE ON SPECIFIC MEASURABLE GOALS TO ACHIEVE WITH THE TARGET POPULATION AND DEFINE EFFICIENT MECHANISMS TO TRACK PROGRESS TOWARD THESE GOALS.

Aiming for a specific goal can help motivate stakeholders; they can measure the progress being made and see a defined endpoint. **We believe that carefully choosing specific measurable goals will ultimately prove critical to the success of the work to come. Once specific goals have been articulated, potential actions should be prioritized in light of their potential for achieving those goals.** If a proposed action would not make achieving a goal more likely, then it should receive lower priority or simply not be taken. The activities developed as part of Recommendation 5 should be shaped and directed by the objectives that are defined here. In other words, this recommendation concerns broader objectives, such as the areas in which to set goals and how much to attempt to achieve, while Recommendation 5 focuses on identifying, e.g., the specific measures to use to gauge progress.

Both outcome and process goals should be contemplated. In terms of outcome goals, the primary point of improving secondary fracture prevention is obviously to lower the incidence of secondary fractures and decreasing fracture rates by a specified percentage would be an outcome goal to consider.<sup>13</sup> Other clinical outcomes, however, are closely related. For example, one of the worst aspects of hip fractures for many patients is the accompanying loss of independence. Reducing the loss of independence, mobility, or other functional outcomes, then, should also be considered for goals, as should the ultimate outcome of mortality.

In considering possible goals for reducing fracture rates, it is useful to review what various existing programs have been able to accomplish. Kaiser Permanente Southern California's Healthy Bones Program, for example, was able to achieve a 40% reduction in hip fractures over two years compared to the expected number by focusing efforts on the patients at highest risk for hip fractures, among other things.<sup>14</sup> Implementation of a fracture liaison service ("FLS") for patients with non-vertebral fractures at a site in the Netherlands cut the rate of second non-vertebral fractures by more than 50% over two years.<sup>15</sup> In Australia, patients with minimal trauma fractures who were treated at a hospital with an FLS program had around 40% fewer major fractures over three years than patients treated at a comparable hospital without an FLS.<sup>16</sup> These rough benchmarks suggest that in individual hospitals or systems that implement full programs, major secondary fractures might be reduced by 40% to 50% over two to three years. When considering the full Medicare population of the US, however, such outcomes would be unachievable absent *nationwide* adoption of effective secondary fracture prevention programs within two years, which obviously is not realistic. **We strongly recommend that reducing secondary fracture rates be adopted as a primary goal**, if logistically feasible, but leave the choice of type of fracture and target percentage reduction to be chosen by the stakeholders involved with developing the Action Plan.

At this point, we note that, as a general matter, we believe that specific quantitative goals are best determined in conjunction with the partners during the development of the Action Plan. Many of the issues involved with determining what goal level is most appropriate are complex and others require value judgments. The stakeholders participating in the next step of the project bring their own knowledge, expertise, experience, and values and we believe they are in the best position to help finalize numerical goals that will be challenging but still feasible to meet.

Mortality is less commonly reported as an outcome in FLS studies but may also be affected. In the study from the Netherlands cited above, not only did an FLS program lower fracture rates, but it significantly

reduced two-year mortality with a hazard ratio of 0.65.<sup>15</sup> Interestingly, a study of patients with primary hip fractures at 11 hospitals in a region of England that had instituted either nurse-led FLS programs or orthogeriatric programs showed that both types of programs significantly reduced both 30-day and one-year mortality (30-day HRs = 0.80 and 0.73, respectively; one-year mortality HRs = 0.84 and 0.81), even though they did *not* significantly reduce second hip fractures.<sup>17</sup> These studies suggest not only that drops in mortality can be observed following implementation of secondary fracture prevention programs, but that they can be observed within a relatively short time period of one to two years. Stakeholders who commented on the draft Strategic Roadmap, however, recommended not choosing mortality reduction as a goal because they believed it would be a less sensitive measure than other options. **We recommend that mortality be followed but that no goal regarding mortality be set.**

Functional outcomes, such as mobility or independence, are relevant and important, but more difficult on which to gather data. Unlike fractures or death, which are likely to be captured in various medical and other records, mobility and independence are considerably less likely to appear in clinical or other records, particularly in an easily accessible format. We thus **do not recommend setting goals of reduction of loss of function** at this time.

Turning to process goals, the main objective is to improve the appropriate evaluation and treatment of the target population. Most of the existing quality measures relating to osteoporosis and secondary fracture prevention are process measures that look to whether procedures are followed and certain actions taken. It is important to note, however, that patients have varying clinical needs and the optimal level of any given process or intervention may not necessarily be 100%. For example, not all patients are good candidates for pharmacologic treatment and a goal of 100% of patients receiving medication would not be medically appropriate.

An ASBMR Task Force on Secondary Fracture Prevention concluded that the most effective secondary fracture prevention programs were case management-type programs like FLSs and the American Orthopaedic Association's Own the Bone<sup>®</sup> program.<sup>18</sup> We believe an aspiration to **increase the number of patients followed up through case management-type programs** would be a meaningful process goal. In order to establish a specific objective, however, such as a 25% increase by 2020, it will be necessary to be able to make accurate measurements of items like the number of FLS programs presently existing and the number of patients who have utilized their services. The National Bone Health Alliance ("NBHA") is presently undertaking an effort to develop more complete data on the number and location of FLS programs in the US and would be a valuable contributor to evaluating this goal. The International Osteoporosis Foundation ("IOF") tracks information on FLS programs internationally and, through its "Capture the Fracture" initiative, evaluates programs' progress based on the extent to which the programs have been able to meet thirteen best practice standards (possible levels include gold, silver, bronze, and unclassified).<sup>19</sup> Other possible goals might include increasing the number of FLS-type programs by a set amount or percentage, increasing the number of FLS-type programs that meet specified quality standards, and increasing the percentage of primary care physicians who are notified of their patient's fracture. In setting the goal(s) for FLS-type programs, it must be kept in mind that such programs will not necessarily be the best models for any given health care setting and that they have relatively high implementation costs – both of which factors will limit the highest level that can be reached.

Case management-type programs represent one method of implementing behavioral changes. There are other models, however, such as the American Heart Association's "Get With the Guidelines<sup>®</sup>" programs, which include other elements like template order sheets for addressing osteoporosis in hip

fracture patients while they are hospitalized or discharge checklists. Process measures focused on **the level of implementation of the most effective elements of such programs** would also be good candidates for consideration.

Interventions for preventing fractures are often considered to belong to one of three categories: fall prevention, medication, or lifestyle changes. Fall prevention might begin with an individual fall risk assessment (e.g., review of medications, vision correction, assessment of balance capabilities) or home fall risk assessment, followed by selective interventions. The CDC divides fall prevention activities for community-dwelling adults into four categories: exercise-based interventions (such as balance training), home modification interventions, clinical interventions (e.g., diet and vision) and multi-faceted interventions.<sup>10</sup> **Possible process goals include increasing the percentage of patients with a documented individual fall risk assessment, increasing the percentage of patients whose homes are “fall-proofed,” or increasing the percentage of patients who exercise and receive balance training, among others.**

With respect to medication use, **we recommend a goal of increasing drug therapy in the target population of patients who are at least 65 years old and who have suffered a hip or vertebral fracture, as defined above.** Too few people with a history of fracture are using drugs that could reduce their risk of future fracture: estimates of osteoporosis medication use in this population following fracture vary from 6%-7%<sup>20</sup> to around 20%,<sup>21,22</sup> far below optimal levels. This goal should be pursued in tandem with efforts to ensure that primary care clinicians are familiar with current knowledge on how to potentially minimize the risk of serious adverse events. In advocating this goal, we are cognizant of implied messages. Setting a goal of increasing the rate of medication use could give the impression to skeptics that this initiative is ultimately about “pushing drugs,” with all the negative connotations that term brings forth. Nevertheless, the scientific evidence supporting this intervention is very strong and the goal of increasing medication use is but one part of a multi-faceted campaign. The situation is analogous to treatment of patients who have suffered a heart attack – patients are counseled regarding changes to diet and exercise but still need to be placed on medications. Although not all fracture patients are candidates for osteoporosis medication, achieving high levels of use appears to be feasible. The Geisinger Health System’s HiROC FLS program, for example, has resulted in around 80% of high-risk patients receiving treatment versus a 32% treatment rate for high risk patients not enrolled in the program.<sup>23</sup>

Lifestyle-directed interventions, the third category in addition to fall prevention and medication use, include reducing alcohol and tobacco use, maintaining adequate intake of calcium and vitamin D, and exercising to build bone strength, among others. **Possible goals could involve increasing the percentage of patients who receive counseling regarding these issues or increasing the percentage of patients who take the recommended actions.**

Whether to choose a specific objective depends in part on the ability to determine that an objective is being achieved at a reasonable cost. If this situation is not the case, perhaps other targets would be better choices. As part of the review of lessons learned, look for existing resources that could be adapted, expanded, or used as models. One key aspect of the “Own the Bone®” program, for example, is a web-based registry in which clinicians can enter a few key pieces of data that can be used to track program success. Another relevant factor is the setting in which the measurement is taken: some data are easier to collect in closed or integrated health systems. Ideally, a simple audit tool that could be used in any setting could be developed.

#### 4. COLLECT AND ANALYZE LESSONS LEARNED FROM SELECTED PAST PROGRAMS AND INITIATIVES.

- a. *Drawing on published reports, expert input, etc. – determine what programs and approaches have worked well, which have not worked, and the most likely explanations for success or lack thereof.*
- b. *Be very cautious about repeating modest variations of programs that have failed.*

In order to efficiently use available resources, it is important to avoid both “reinventing the wheel” for effective initiatives and failing to learn from history regarding less successful programs. Relevant programs thus need to be identified and reviewed for what they can teach us. In terms of identifying programs, there are a number of sources readily available. First, the ASBMR Task Force Report on Secondary Fracture Prevention summarized in 2012 the evidence in the literature for and against specific interventions aimed at preventing secondary fractures.<sup>18</sup> In so doing, the Task Force referenced numerous national and international programs and initiatives. (It should be noted that, since that report, there has been much greater implementation of FLSs worldwide and it would be worthwhile to also study the content and effectiveness of these newer programs.) Secondly, the NBHA is in the process of surveying its members regarding relevant programs they are directing and has indicated it will share that information with ASBMR. Thirdly, international organizations such as the IOF and Fragility Fracture Network (“FFN”) have established and supported numerous projects and have a great deal of accumulated knowledge from which they either already have distilled or might distill significant lessons. They also may be aware of models of care coordination or other interventions that would work well in a US setting.

Some of the larger fracture prevention projects focusing on bone health that may be worth examining include:

- International Osteoporosis Foundation’s “Capture the Fracture”<sup>19</sup>
- National Bone Health Alliance’s “2 Million 2 Many,”<sup>24</sup> “Secondary Fracture Prevention Initiative,”<sup>24</sup> and “20/20 Vision”<sup>24</sup>
- American Society for Bone and Mineral Research’s “Call to Action”<sup>25</sup>
- American Orthopaedic Association’s “Own the Bone”<sup>®1</sup>
- Bone and Joint Decade’s “Fragility Fracture Network”<sup>26</sup>

Similarly, several programs dedicated to reducing the risk of falling have been developed or are in the process of implementation, including:

- Center for Disease Control and Prevention’s “Stopping Elderly Accidents, Deaths, and Injuries” (“STEADI”)<sup>27</sup>
- AARP’s and United Healthcare’s “Fall Prevention Challenge”<sup>28</sup>
- National Council on Aging’s “Stay Active and Independent for Life” (“SAIL”)<sup>29</sup>
- Pennsylvania Department of Aging’s “Healthy Steps for Older Adults”<sup>30</sup> / “Healthy Steps in Motion”<sup>31</sup>

Given the number and variety of bone health and fracture prevention programs, it will be necessary to develop criteria for prioritizing initiatives to review. Given the focus of this project, we believe that top

priority for review should be given to programs that included a primary care clinician engagement component. Programs that did not include such a component are less likely to provide the most useful information for moving this initiative forward.

**Not only will examining selected programs on bone health and fall prevention provide valuable information to help determine the content of this initiative, but it can also help identify resources or programs that potentially could be utilized to support this effort.** The AOA's "Own the Bone<sup>®</sup>" program, for example, incorporates a web-based registry for de-identified patient data, including fracture history, medication use, bone mineral density testing results, and other relevant information. Additionally, the NOF/NBHA's "Qualified Clinical Data Registry" (QCDR) has been approved by the Centers for Medicare and Medicaid ("CMS") to support better outcomes by tracking performance against quality benchmarks, using automated electronic health record data, and qualifying clinicians to receive bonus payments and avoid penalties. These programs could serve as models for other quality improvement or data collection efforts or perhaps could itself be expanded and used more broadly to help measure changes in care and outcomes. Also, as mentioned elsewhere in the Roadmap, international programs' achievements could potentially be used as benchmarks for assessing the success of US efforts.

**Other public health programs in different disease areas can also provide important lessons.** For example, the American Heart Association's ("AHA's") "Get With The Guidelines<sup>®</sup>" ("GWTG") project was a hospital-based quality improvement initiative to reduce death and disability due to cardiovascular disease and stroke by focusing on compliance with secondary prevention clinical guidelines before discharging patients who had survived a myocardial infarction.<sup>32</sup> Elements of the initiative included a Web-based system requiring about 90 seconds of data entry that also provided specific recommendations on how to comply with the guidelines and generated a letter to the patient's primary care practitioner that documented the discharge orders.<sup>32</sup> The published literature on GWTG includes articles on program implementation,<sup>33</sup> outcomes,<sup>34</sup> and registry development,<sup>35,36</sup> among other topics. Because many of the identified barriers to secondary fracture prevention are similar to the barriers that GWTG was designed to address,<sup>33</sup> one would reasonably expect to obtain relevant information by reviewing specific aspects of the initiative. In fact, the AOA's Own the Bone<sup>®</sup> program was modeled on GWTG and was developed with the guidance of the American Heart Association.<sup>37</sup> (NOTE: The AHA has since expanded its GWTG program to include stroke, heart failure, resuscitation, and atrial fibrillation,<sup>38</sup> all of which may demonstrate how the initial principles can be adapted to other clinical settings.)

**Another area not directly related to preventing fractures that may be fruitful to explore would be programs to engage and activate clinicians, especially primary care clinicians.** Most of the literature in this area appears to be focused on quality improvement. The issues are complex, however, and relevant insights may be difficult to identify. The effectiveness of financial incentives for changing practitioner behaviors, for example, appears to be a matter of some dispute with some reviewers concluding that the importance of financial incentives is often overemphasized<sup>39</sup> and others focusing solely on strategies to make incentives work better.<sup>40</sup> It may prove most productive to focus this area of research on reliable reviews from trustworthy sources. The Agency for Healthcare Research and Quality, for instance, recently summarized strategies for engaging primary care practices in quality improvement initiatives,<sup>41</sup> and the National Academy for State Health Policy has provided an overview of states' efforts to engage primary care clinicians in pediatric oral care services.<sup>42</sup> The NHLBI Implementation Science Work Group also recently published a report on selected clinical practice guideline implementation strategies.<sup>43</sup>

Public health campaigns focused on other aspects of bone health and fracture prevention, such as improving peak bone mass early in people's lives, may also help provide insights into peoples' attitudes and beliefs, but should *not* be prioritized for review at this time. For example, programs such as "Milk Matters," a calcium educational campaign developed by the National Institute of Child Health and Human Development,<sup>44</sup> and "Best Bones Forever!," a bone health campaign from the Office of Women's Health at HHS,<sup>45</sup> stressed the importance of calcium and vitamin D intake and exercise in girls and young women to build peak bone mass. While those campaigns, targeted primarily at mothers and daughters, did not address issues relating to adult osteoporosis, their content theoretically might help explain why large numbers of women believe that osteoporosis can be adequately managed by just diet and exercise. Even if there were any relationship, however, any change in program content now would not be expected to provide benefit for decades.

## **5. EVALUATE AND PRIORITIZE ACTIVITIES DESIGNED TO ACHIEVE THE GOALS DEFINED ABOVE.**

- a. Agree on a core set (5-7) of meaningful process and outcome measures to evaluate quality of care in the target patient population.*

**Tracking the progress of the activities conducted as part of this initiative will be supported and guided by the selection of a "core set" of quality measures that are explicitly linked to the target population, interventions and goals selected for the initiative. We suggest the following approach to identifying measures to be included in the core set.**

The first step is to survey the landscape by gathering together currently-existing quality measures and information about who is using them. Key stakeholders with experience using quality measures should be consulted. The AOA's "Own the Bone<sup>®</sup>" program, for example, includes a set of ten process measures. The NOF and NBHA have developed a Quality Improvement Registry that has been approved by CMS as a Qualified Clinical Data Registry and that contains 43 quality measures.<sup>46</sup> Experience from these programs and others such as IOF's "Capture the Fracture" program, can provide insight into the usefulness of existing measures, applicability to the goals articulated in the Call to Action, and guidance on identifying additional measures that may be useful, if needed.

Several other sources of relevant information should also be reviewed. The National Quality Forum ("NQF"), for example, endorses seven measures relating to care of people with osteoporosis, a few of which pertain specifically to secondary fracture prevention (0045: "Osteoporosis: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older"; 0053: "Osteoporosis Management in Women Who Had a Fracture").<sup>47</sup> Interestingly, in 2013 the NQF retired a measure relating to use of pharmacological treatment for osteoporosis;<sup>47</sup> exploring the rationale for that decision may provide helpful insights. The Healthcare Effectiveness Data and Information Set ("HEDIS"), maintained by the National Committee for Quality Assurance and used by the Centers for Medicare and Medicaid Services ("CMS") to assess certain Medicare Advantage plans, contains two measures for osteoporosis care, one of which relates to secondary fracture prevention.<sup>48</sup>

CMS's Merit-based Incentive Payment System ("MIPS") also includes a number of quality measures relating to osteoporosis, although their specific use is not mandated -- physicians choose which quality measures they want to utilize.<sup>49</sup> Similarly, the Joint Commission has recommended evidence-based performance measures published in the monograph, "Improving and Measuring Osteoporosis

Management"<sup>50</sup> and finalized three performance measures for hospitals,<sup>51</sup> although these have yet to be implemented and there are no current plans for implementation. Finally, one of the most comprehensive sources of information about quality measures is the Agency for Healthcare Research and Quality's National Quality Measures Clearinghouse ("NQMC"), which has the mission "to provide an accessible mechanism for obtaining detailed information on quality measures, and to further their dissemination, implementation, and use in order to inform health care decisions."<sup>52</sup> The survey should include these sources at a minimum.

The candidate measures should then be reviewed to judge their relationship to the goals articulated as part of Recommendation 3, their potential to make achieving those goals more likely, and the feasibility of their use for the target population.

***b. Meet with CMS to explore potential mechanisms to pay for case management programs and/or apply value-based payment incentives to care of these patients.***

At the July 19<sup>th</sup> multi-stakeholder summit, it was noted that several mechanisms presently exist through which Medicare might reimburse secondary fracture prevention services. Other mechanisms could potentially be used as well, although sufficient evidence would need to be available to support their utilization. One specific example involves how a fracture liaison service coordinator might be paid for under Medicare. The upfront financial costs of hiring dedicated personnel and instituting an FLS program are known barriers to FLS implementation and some academic institutions have been unable to financially sustain these programs.<sup>53</sup> Developing a possible pathway to fund FLS coordinators could make a substantial difference in whether and how quickly institutions might adopt case management models for secondary fracture prevention.

Stakeholders have identified other potential topics for discussion with CMS as well. Increasing reimbursement to primary care clinicians for providing care and counseling to patients with osteoporosis is one topic. Osteoporosis subjects needing explanation and counseling are numerous, but time spent providing such care is often undervalued relative to more procedure-based care. Another topic to discuss with CMS might be administrative barriers to providing intravenous bisphosphonates (or, potentially, coverage of new and innovative therapies). For example, some Medicare Administrative Contractors require practitioners to explain why oral bisphosphonate therapy has failed or is contraindicated before covering intravenous therapy.<sup>54</sup> Thirdly, several stakeholders noted their concerns about reimbursement rates for DXA scans and the resulting impact on patient care. This topic is an important one, but we are aware of existing and ongoing efforts to address the issue and would advise that those activities continue rather than be imported into this project, particularly given the project's purposely well-circumscribed focus. Another possible topic might be tying reimbursement for care of fracture patients to meeting quality / value based standards.

**Entering into a dialogue with appropriate CMS personnel regarding potential payment mechanisms and supporting evidence is worth pursuing. One first step in that process might be to hold an initial discussion with leaders of the Center for Clinical Standards and Quality ("CCSQ") (e.g., Kate Goodrich and Shari Ling) and the Center for Medicare and Medicaid Innovation ("CMMI") to discuss the concept and identify mechanisms available to CMS.** Stakeholders could then develop and elaborate on a proposal to submit to CMS that could provide a basis for discussions on potential ways of moving forward. This undertaking will require substantial planning and effort, yet because of the magnitude of the possible impact, many stakeholders support this activity and we believe it should be pursued. We do caution that, in exploring mechanisms, care needs to be taken not to interfere with care



management payment systems currently in use in primary care (e.g., shifting existing chronic care management payments in order to provide osteoporosis care would compromise other important health objectives).

- c. Review existing clinical guidelines from primary care and specialty organizations to determine whether the high priority target population and proposed interventions are consistent with them. Based on the advice in this Roadmap and the review of clinical guidelines, develop a short, simple, clinical recommendation for the target population. Disseminate the recommendation in trusted and prominent publications.***

One of the issues most consistently identified by stakeholders as problematic is the existence of multiple relevant clinical guidelines, written from different perspectives and advising different actions. These inconsistencies result in primary care provider confusion and inertia. Given their patients' competing clinical problems and their own time pressures, it should not be surprising that front-line clinicians may not prioritize fracture prevention, bolstered by the perception that "no-one knows the right thing to do." The variations are most striking in areas of clinical decision-making where the evidence is not clear, but also reflect the differences between approaches taken by primary care clinicians and by various specialists. However, one advantage of targeting a patient population for which the evidence of high fracture risk and effective therapies is so strong is that discrepancies between relevant guidelines are less likely to exist. While harmonizing existent guidelines in all areas would probably be impossible to achieve, reaching consensus on management of patients at highest risk is a feasible goal.

**Any inconsistencies between the existing clinical guidelines for the identified target population should be examined and considered carefully to determine whether the target population, interventions and outcomes need to be further refined.**

**We suggest that the next step after reviewing clinical guidelines should be to develop a statement or recommendation for the target population *de novo*.** The statement should not oversimplify the medical consensus and should include guidance on when primary care clinicians should consult specialists. Patient and primary care stakeholders should be involved with both developing and revising the recommendation.

Although knowledge in and of itself is usually insufficient to lead to change, providing it is a necessary first step.<sup>33</sup> Thus, we suggest that when a consensus is reached among participating groups on a high-risk population and on a short, simple, clinical recommendation for that population, one or more articles should be prepared for nationally prominent publications that are widely used and trusted by primary care clinicians. The online publication UptoDate,<sup>55</sup> for example, is an essential resource for clinicians looking to remain current with the latest thinking on best practices for patient care. Articles should include information on the specific population targeted and recommended alternatives for care, which could include drug treatment, falls prevention, nutrition and exercise recommendations, information on fracture liaison services, etc. With respect to drug therapy, articles should clearly provide updated information on possible adverse events and current knowledge on best practices to potentially minimize the risk of these events. These articles should be prepared in collaboration with participating partners on the initiative and include a statement of support from backing organizations.

- d. Work with patient, primary care, and specialist partners to support broad circulation of the short, simple, clinical recommendation as well as the Action Plan (mentioned in #1 above) to their respective members / constituents.***

Consistent with Recommendation 1 above, partnering organizations should take an active role in disseminating key information to their membership. Professional groups such as the American College of Physicians and the American Academy of Family Physicians are well positioned to circulate this information to their membership in a targeted and relevant way. Each organization likely has developed its own communication style that it finds to be effective in reaching its members, whether through paper journals, websites, email updates, social media, or other mechanisms, and can highlight aspects of the clinical recommendation and Action Plan that are particularly relevant to their members.

The primary care setting is a vital link in assuring patients who have already had a fracture receive appropriate care, hence is a focus for communication in this plan. As noted above, a range of health care professionals may interact with the patient over the course of a care episode, and many of these individuals may spend more time with the patient and have more opportunity for discussion than the physician. For these reasons, responsibility for identifying at-risk patients, assessing their needs, and assuring they receive appropriate care cannot solely fall to the primary care physician. Organizations representing these other front-line health professionals, such as occupational therapists, physical therapists, rehabilitation center specialists, physician assistants, nurse practitioners, etc., should be actively engaged in the initiative to educate their members on identifying at-risk patients, assessing whether patients are receiving appropriate care, and providing guidance to patients who may not have been provided adequate information on risk and treatment options. As noted in Recommendation 1, these groups should be engaged as partners in preparing and disseminating the Action Plan, and representatives of these groups should be willing to help disseminate relevant and targeted information to their membership to help insure that high-risk patients are not slipping through the cracks of the system.

***e. Develop and circulate educational material for patients, primary care clinicians, and specialists that highlight clinical recommendations that are aligned with project goals.***

Materials should be prepared that specifically focus on communicating that men and women at or over 65 years of age who have had a hip or vertebral fracture are at high risk of suffering another one. These risk communication materials can be tailored for different stakeholders and for different stages of the clinical care pathway. Patients who have had a previous fracture that is now mended, for example, may believe that the fracture is a closed chapter and not important information to disclose. Direct messaging to patients could include a reminder to “tell your doctor” if you have been treated for a hip or vertebral fracture. In this way, patients may become more aware of the importance of this disclosure for future care. Risk communication materials designed for patients (“tell your doctor”) could also be provided as reading material or as posters in waiting areas or examination rooms. Simple reminders posted on walls can be surprisingly powerful agents of behavioral change.<sup>56</sup>

As noted above, there are many health care professionals, such as physician assistants, nurse practitioners, and office staff, who sometimes spend more time with patients than do physicians. Messaging to primary care physicians and other front-line professionals could include similar reminders to ask patients who are 65+ years of age if they have had any falls or received any care for hip or vertebral fractures.

While the focus of this document is on engaging primary care clinicians, a recognized challenge of secondary fracture prevention is that the surgeons, hospitals, and rehabilitation centers where patients receive initial treatment for fractures may never relate the patients’ experience with them back to the

primary care setting. Thus, to help fill what has been an important communication gap, communications of this initiative should also be designed for orthopedists and other care providers who are among the first to see a patient after a fracture. Communication should remind these clinicians to inform their patients regarding secondary fracture risks and advise them to inform and consult with their primary care physician.

## **6. CONSIDER PARTNERSHIPS WITH INTEGRATED HEALTH CARE DELIVERY SYSTEMS TO DEVELOP SYSTEM-SPECIFIC PROGRAMS TARGETED TO PREVENT SECOND FRACTURES.**

- a. Ideally focus on those with, for example, low rates of drug treatment and case management use, or other measures consistent with those identified in Recommendation 3.*
- b. Pilot studies may allow for refinement of target population, interventions, collection of process and outcomes data.*

Integrated health care delivery systems (“IDSs”) are health systems in which primary care and specialty services are integrated within the same administrative network under the ownership of a single parent company. These systems provide a continuum of care for patients who are members in system health plans. These organizations offer centralized policies for care, centralized data collection systems, and incentives aligned with tracking process measures and outcomes for more effective and cost-efficient care. **These characteristics make them potentially ideal grounds for pilot programs to prevent secondary fractures in the high-risk target population identified.**

Thought will need to be given to criteria for the health systems that might best serve as partners in this effort. Seeking partnerships with the largest IDSs may provide opportunities for reaching a large target population for secondary fracture prevention. However, if these large health systems already have in place effective programs to treat patients at high risk of second fractures, then there is little need for intervention at the system level. Hence, it would be useful to have access to information on system policies, programs, and performance metrics. Some of this information may be publicly available, as providers and public and private health plans increasingly publish performance data. CMS’s Hospital Compare website publishes quality performance data on hospitals in the Medicare program.<sup>57</sup> CMS also reports quality data for the Medicare program on nursing homes, Medicare Advantage plans, and home health agencies. While these metrics are not specifically designed to track patients at high risk for fractures, some metrics may provide useful information on hospitals, nursing homes, and other facilities that are part of candidate integrated health systems. For example, one quality measure in CMS’s Nursing Home Compare database is “[p]ercentage of long-stay residents experiencing one or more falls with major injury.”<sup>58</sup> The Veterans Healthcare Administration (“VHA”), the largest IDS in the United States, is another system for which quality and other data are readily available and it already has conducted relevant innovative studies, e.g., assessing a program that uses clinical pharmacists to identify patients who have fractured but not received treatment for osteoporosis.<sup>59</sup> Another useful approach might be to look for IDSs lacking a fracture liaison service, as these systems are likely to be less focused on effective post-fracture care and prevention.

**Integrated health systems that have geographically stable patient populations (relatively speaking) would also be desirable as partners because these systems will have well aligned incentives to prevent long-term adverse outcomes and an ability to track patient outcomes over longer periods.** The Medicare population in integrated health systems should be expected to be particularly stable in

this sense. IDs participating as partners in the program would need to be willing to implement new quality performance measures consistent with the goals of this program, the initiation of which may incur some administrative cost. If successful, however, this cost should be more than offset through preventing second fractures in high-risk patients.

Programs are not always easily transferable from integrated systems to non-integrated systems because of the different organizational and personnel structures, responsibilities, and incentives. Nevertheless, lessons and principles learned from pilot programs in IDs would not only be directly pertinent for other IDs but could potentially be adapted for other types of health care systems as well.

## **7. ALIGN SEPARATE PR / MEDIA ACTIVITIES (SUCH AS NBHA, NIAMS, OTHERS) WITH CORE ELEMENTS OF THIS STRATEGIC ROADMAP**

As noted, many groups have parallel or related programs for bone health, fracture prevention, falls prevention, building osteoporosis awareness, etc. Conflicting or inconsistent messaging from different groups around these themes can only contribute to a continuing sense for patients and providers that “nobody knows what to do” and “it’s all too complicated.” **For this reason, to the extent that messaging for these programs aligns with central elements of the revised Call to Action, effort should be made to align the messages presented by these groups.** Consideration should be given not only to messaging of US-based programs and initiatives, but also international efforts by groups such as the IOF. Memoranda of understanding among the key organizations and government agencies would be useful tools to insure that parties are kept informed of proposed initiatives and have the opportunity to comment or provide input.

That said, the earlier caution (from Recommendation 1) still stands that some of the groups having parallel or related initiatives receive significant funding from industry sources and may be perceived by some stakeholders as “captured” by industry interests. Care should be taken that aligning messaging in ways intended to avoid confusion is not seen as being industry-driven.

## **PRIORITIZING ACTIVITIES**

**While this Roadmap begins with what may be the most critical element of collaboration to achieve success – relationship-building with patient and primary care professional groups (Recommendation 1) – extending invitations to these groups for partnership on an Action Plan should be concurrent with efforts to review the lessons learned from other relevant initiatives (Recommendation 4), since applicable lessons should be taken on board and built into the design of this initiative before significant work on implementation is begun.** Then, the work of developing the Action Plan with these partners will entail establishing consensus on the target population (Recommendation 2) and on the specific goals and measures that will be used to assess progress (Recommendation 3). Once the Action Plan has been developed, patient and primary care volunteers or “champions” would help with communication, messaging, education, and other key activities through their organizations and beyond (Recommendations 1 and 5). Planning for this messaging, as well as for media announcements and attempts to align messaging with existing related initiatives (Recommendation 7) would take place as part of a comprehensive communications plan that should be developed as the Action Plan approaches completion. At that time, discussions could begin with prospective integrated health systems for potential process improvement programs and an initial

meeting could be planned for discussion of mechanisms and evidence for coverage of case management programs.

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## APPENDIX A FRACTURE PREVENTION STAKEHOLDER SUMMIT

### Participant List

July 19, 2017 | Crystal City, VA

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