

More Cancer Survivors Need More Research

BY KERRI WACHTER
FROM MMWR

The number of cancer survivors in the United States rose from 3 million in 1971 and 9.8 million in 2001 to 11.5 million in 2007, according to a new report by the Centers for Disease Control and Prevention and the National Cancer Institute.

The numbers come from the study "Cancer Survivors in the United States, 2007" (MMWR 2011;60:269-72). The study authors defined a cancer survivor as "a person living with a history of cancer."

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The rising number – 11.5 million in 2007 – highlights the need for more research on the unique physical, psychological, and social issues that face cancer survivors.

growing number of people who have faced a cancer diagnosis which affects them and their loved ones – from the time of diagnosis through the rest of their lives," the NCI's Julia H. Rowland, Ph.D., said in a press release.

"Unfortunately for many cancer survivors and those around them, the effect of cancer does not end with the last treatment. ... This report underscores the need for continued research, as well as for the development and implementation of best practices to provide optimal care and support for all cancer survivors," said Dr. Rowland, director of the NCI's Office of Cancer Survivorship.

The study authors analyzed the number of new cancer cases (except in situ and nonmelanoma skin cancers) as well as follow-up data from the NCI's SEER (Surveillance, Epidemiology and End Results) program in 1971-2006. They estimated the number of persons who were ever diagnosed with cancer and were alive on Jan. 1, 2007 (MMWR 2011;60:269-72).

Notably, 65% of cancer survivors on Jan. 1, 2007, received their diagnosis at least 5 years earlier. Also, people aged 65 years or older accounted for 60%. The largest group of cancer survivors was breast cancer survivors (22%), followed by prostate cancer survivors (19%) and colorectal cancer survivors (10%). Women accounted for slightly more than half (54%) of all survivors.

Clinicians can find research tools, publications and other resources through the NCI's Office of Cancer Survivorship at <http://cancercontrol.cancer.gov/ocs/>.

Prevention Lacking in Older Americans

BY HEIDI SPLETE

Millions of Americans aged 65 years and older are not receiving potentially lifesaving preventive services, according to a report that was issued by the Centers for Disease Control and Prevention and the U.S. Department of Health and Human Services.

Approximately 85% of flu-related deaths and 63% of flu-related hospital-

izations occur in adults aged 65 years and older.

Data have shown that use of the pneumococcal vaccine is a cost-effective way to improve survival and reduce hospital stays in older adults who have community-acquired pneumonia, according to the authors of the report, "Enhancing Use of Clinical Preventive Services Among Older Adults: Closing the Gap."

However, in 2009, more than 31% of

older adults had not received an influenza vaccination in the past year, while more than 33% reported that they had never received a pneumococcal vaccination.

The report included eight indicators to measure the use of clinical preventive health services by American adults aged 65 years and older: influenza vaccination; pneumococcal vaccination; counseling for smoking cessation; and screening for breast cancer, colorectal

In addition to diet and exercise to improve glycemic

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(saxagliptin and metformin HCl
extended-release) tablets

1 **ONE DAILY DOSE** The first and only once-a-day metformin XR + DPP-4 inhibitor* combination tablet.

Generally taken once-daily with evening meal; gradually titrate dose to reduce GI side effects associated with metformin. Maximum daily recommended dose is 5 mg saxagliptin and 2000 mg metformin XR that can be taken as two 2.5 mg/1000 mg tablets once a day.

*saxagliptin

Indication and Important Limitations of Use

KOMBIGLYZE XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.

KOMBIGLYZE XR should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

KOMBIGLYZE XR has not been studied in combination with insulin.

Important Safety Information

WARNING: LACTIC ACIDOSIS

Lactic acidosis is a rare, but serious, complication that can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure.

The onset of lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress.

Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.

If acidosis is suspected, KOMBIGLYZE XR should be discontinued and the patient hospitalized immediately.

[See Warnings and Precautions]

Contraindications

- Renal impairment (e.g., serum creatinine levels ≥ 1.5 mg/dL for men, ≥ 1.4 mg/dL for women, or abnormal creatinine clearance)
- Hypersensitivity to metformin hydrochloride
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis
- KOMBIGLYZE XR should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials because use of such products may result in acute alteration of renal function.

Warnings and Precautions

- The reported incidence of lactic acidosis in patients receiving metformin is very low (approximately 0.03 cases/1000 patient-years). When it occurs, it is fatal in approximately 50% of cases. Reported cases of lactic acidosis have occurred primarily in diabetic patients with significant renal insufficiency.
- Patients with congestive heart failure requiring pharmacologic management, in particular those with unstable or acute congestive heart failure who are at risk of hypoperfusion and hypoxemia, are at increased risk of lactic acidosis.
- Lactic acidosis risk increases with the degree of renal dysfunction and patient age. The risk may be significantly decreased by use of minimum effective dose of metformin and regular monitoring of renal function. Careful renal monitoring is particularly important in the elderly. KOMBIGLYZE XR should not be initiated in patients ≥ 80 years of age unless measurement of creatinine clearance demonstrates that renal function is not reduced.
- Withhold KOMBIGLYZE XR in the presence of any condition associated with hypoxemia, dehydration, or sepsis.
- Before initiation of KOMBIGLYZE XR, and at least annually thereafter, renal function should be assessed and verified as normal.
- KOMBIGLYZE XR is not recommended in patients with hepatic impairment.
- Metformin may lower vitamin B12 levels. Measure hematological parameters annually.
- Warn patients against excessive alcohol intake.
- KOMBIGLYZE XR should be suspended for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids), and should not be restarted until patient's oral intake has resumed and renal function is normal.
- Use of saxagliptin or metformin with medications known to cause hypoglycemia
 - Saxagliptin: Insulin secretagogues, such as sulfonylureas, cause hypoglycemia. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia if used in combination with KOMBIGLYZE XR.

Please see adjacent Brief Summary of US Full Prescribing Information including Boxed WARNING about lactic acidosis.

cancer, diabetes, lipid disorders, and osteoporosis.

Breast cancer screening and cholesterol screening were the most widely used services. Only 17% of women aged 65 years and older reported not receiving breast cancer screening in the past 2 years, while only 5% of adults aged 65 and older said that they had not had blood cholesterol screening in the past 5 years.

The report also highlighted ethnic disparities in many of the preventive services for older adults.

Approximately 49% of Asian/Pacific

Islanders and 47% of Hispanics in the United States reported that they had not undergone colorectal cancer screening, compared with 37% of blacks, 35% of American Indians/Alaska Natives, and 34% of whites.

In addition, approximately 51% of Hispanics, 47% of blacks and Asian/Pacific Islanders, and 36% of

American Indians/Alaska Natives reported never receiving a pneumococcal vaccine, compared with 30% of whites.

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The authors of the report recommended a number of interventions for improving preventive care among older adults, including promoting annual wellness visits, reducing barriers to pre-

ventive care services, and tailoring preventive health messages to the needs of each individual.

The report also recommended several additional preventive services that could be used by older adults: screening and counseling for alcohol misuse; zoster vaccination; aspirin use; blood pressure screening; cervical cancer screening; depression screening and counseling; and obesity screening and counseling.

The full report is now available online at <http://www.cdc.gov/Features/PreventiveServices/>.

control in your adult patients with type 2 diabetes when treatment with both saxagliptin and metformin is appropriate



A dynamic duo

Combining complementary mechanisms
of action of saxagliptin and metformin XR

- Adverse reactions reported in $\geq 5\%$ of patients treated with saxagliptin and more commonly than in patients treated with placebo were: upper respiratory tract infection (7.7% vs 7.6%), urinary tract infection (6.8% vs 6.1%), and headache (6.5% vs 5.9%).
- Adverse reactions reported in $\geq 5\%$ of treatment-naïve patients treated with coadministered saxagliptin and metformin immediate-release (IR) and more commonly than in patients treated with metformin IR alone were: headache (7.5% vs 5.2%) and nasopharyngitis (6.9% vs 4.0%).

Drug Interactions: Because ketoconazole, a strong CYP3A4/5 inhibitor, increased saxagliptin exposure, limit KOMBIGLYZE XR to 2.5 mg/1000 mg once daily when coadministered with a strong CYP3A4/5 inhibitor (e.g., atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin).

Use in Specific Populations

- **Pregnant and Nursing Women:** There are no adequate and well-controlled studies in pregnant women. KOMBIGLYZE XR should be used during pregnancy only if clearly needed. It is not known whether saxagliptin or metformin are secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when KOMBIGLYZE XR is administered to a nursing woman.
- **Pediatric Patients:** Safety and effectiveness of KOMBIGLYZE XR in pediatric patients have not been established.

—Metformin: Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use, but could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, during concomitant use with other glucose-lowering agents (such as sulfonylureas or insulin), or with use of ethanol. Elderly, debilitated, or malnourished patients and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects.

- Intravascular contrast studies with iodinated materials can lead to acute alteration of renal function and have been associated with lactic acidosis in patients receiving metformin. KOMBIGLYZE XR should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours after the procedure and reinstated only after renal function is normal.
- There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with KOMBIGLYZE XR or any other anti-diabetic drug.

Adverse Reactions

- Adverse reactions reported in $>5\%$ of patients treated with metformin extended-release and more commonly than in patients treated with placebo were: diarrhea (9.6% vs 2.6%) and nausea/vomiting (6.5% vs 1.5%).

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