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– FOCUS ISSUE –

Humanitarian

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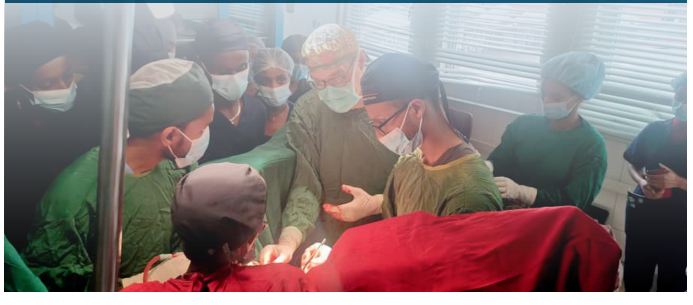

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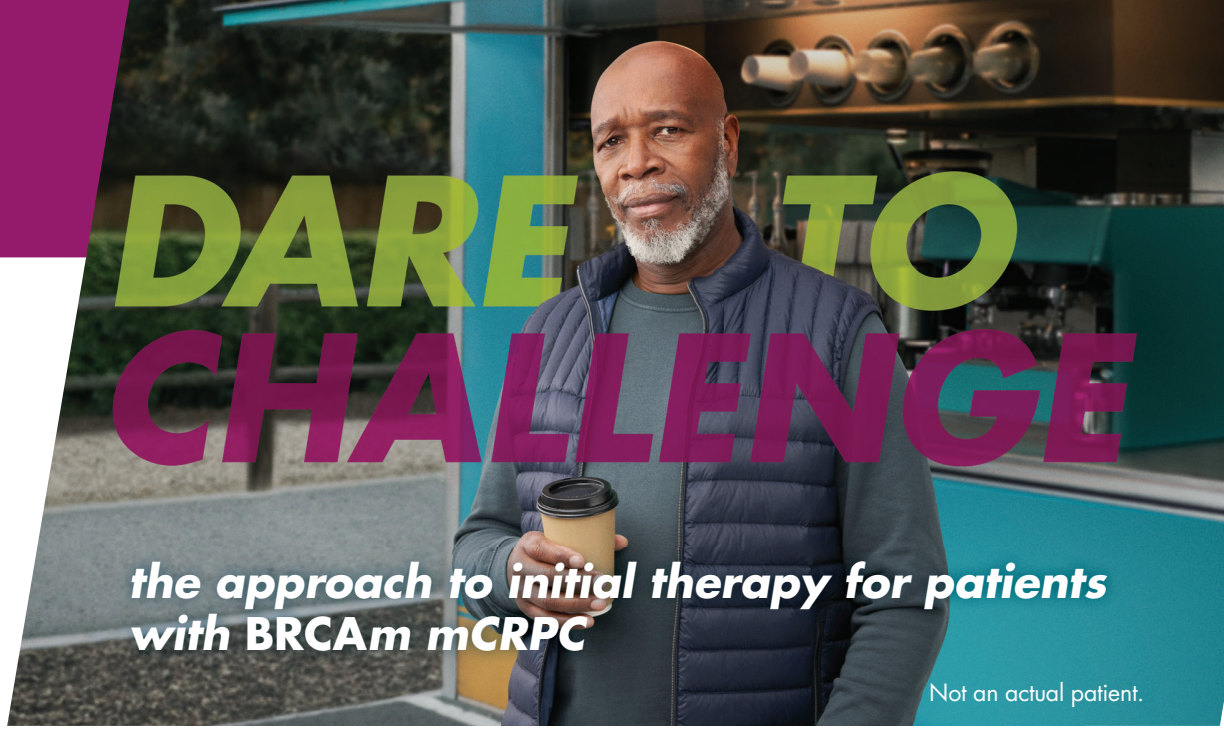


NOW APPROVED

LYNPARZA: the FIRST PARPi approved in combination with abiraterone plus prednisone or prednisolone (abi/pred) as initial therapy for *BRCAm* mCRPC[1-4]

INDICATION

LYNPARZA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated in combination with abiraterone and prednisone or prednisolone (abi/pred) for the treatment of adult patients with deleterious or suspected deleterious *BRCA*-mutated (*BRCA*m) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

PROpel: A phase 3 trial

PROpel examined the efficacy of LYNPARZA + abi/pred vs placebo + abi/pred (active comparator) upon mCRPC diagnosis[1,5]

- PROpel was a randomized, double-blind, placebo-controlled, multicenter, phase 3 trial
- ITT population (N=796): mCRPC with or without HRR mutations
  - **FDA approval of LYNPARZA + abi/pred was based on an exploratory *BRCA*m subgroup (n=85)**
- Patients were randomized 1:1 to receive either LYNPARZA (300 mg BID) + abiraterone (1000 mg QD) with prednisone or prednisolone (5 mg BID) (n=399) or placebo + abiraterone (1000 mg QD) with prednisone or prednisolone (5 mg BID) (n=397). LYNPARZA was continued until objective radiological disease progression determined by investigator or unacceptable toxicity. All patients received a GnRH analog or had prior bilateral orchiectomy
- Patients were stratified by metastatic site and whether they received prior docetaxel at mHSPC stage. *BRCA*m status was not a stratification factor. Prior abiraterone was not allowed

Trial endpoints:

- Primary endpoint (ITT): rPFS by investigator assessment*
- Additional efficacy outcome measure (ITT): Overall survival
- Safety and tolerability
- **Exploratory *BRCA*m subgroup analyses**
  - Investigator-assessed rPFS* and OS in patients with *BRCA*m mCRPC (n=85)
  - Sensitivity analysis of rPFS by BICR

*BRCA*m status was assessed after randomization and before primary analysis by both NGS-based tumor tissue and ctDNA tests. *BRCA*m classification criteria in line with the FDA-approved assays were used to determine the deleterious and suspected deleterious somatic or germline mutation status of patients.

*Radiological progression-free survival (rPFS) assessed by investigator per RECIST v1.1 (soft tissue) and PCWG3 (bone) criteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in approximately 1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was 2 years (range: <6 months to >10 years). All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

Do not start LYNPARZA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt LYNPARZA and monitor blood count weekly until recovery.

If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. Discontinue LYNPARZA if MDS/AML is confirmed.

Pneumonitis: Occurred in 0.8% of patients exposed to LYNPARZA monotherapy, and some cases were fatal. If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a radiological abnormality occurs, interrupt LYNPARZA treatment and initiate prompt investigation. Discontinue LYNPARZA if pneumonitis is confirmed and treat patient appropriately.

Venous Thromboembolism (VTE): Including severe or fatal pulmonary embolism (PE) occurred in patients treated with LYNPARZA. In the combined data of two randomized, placebo-controlled clinical studies (PROfound and PROpel) in patients with metastatic castration-resistant prostate cancer (N=1180), VTE occurred in 8% of patients who received LYNPARZA, including pulmonary embolism in 6%. In the control arms, VTE occurred in 2.5%, including pulmonary embolism in 1.5%. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism, and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating treatment.

Females

Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months following the last dose.

Males

Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of LYNPARZA and to not donate sperm during this time.

ADVERSE REACTIONS—Metastatic Castration-Resistant Prostate Cancer in Combination with Abiraterone and Prednisone or Prednisolone

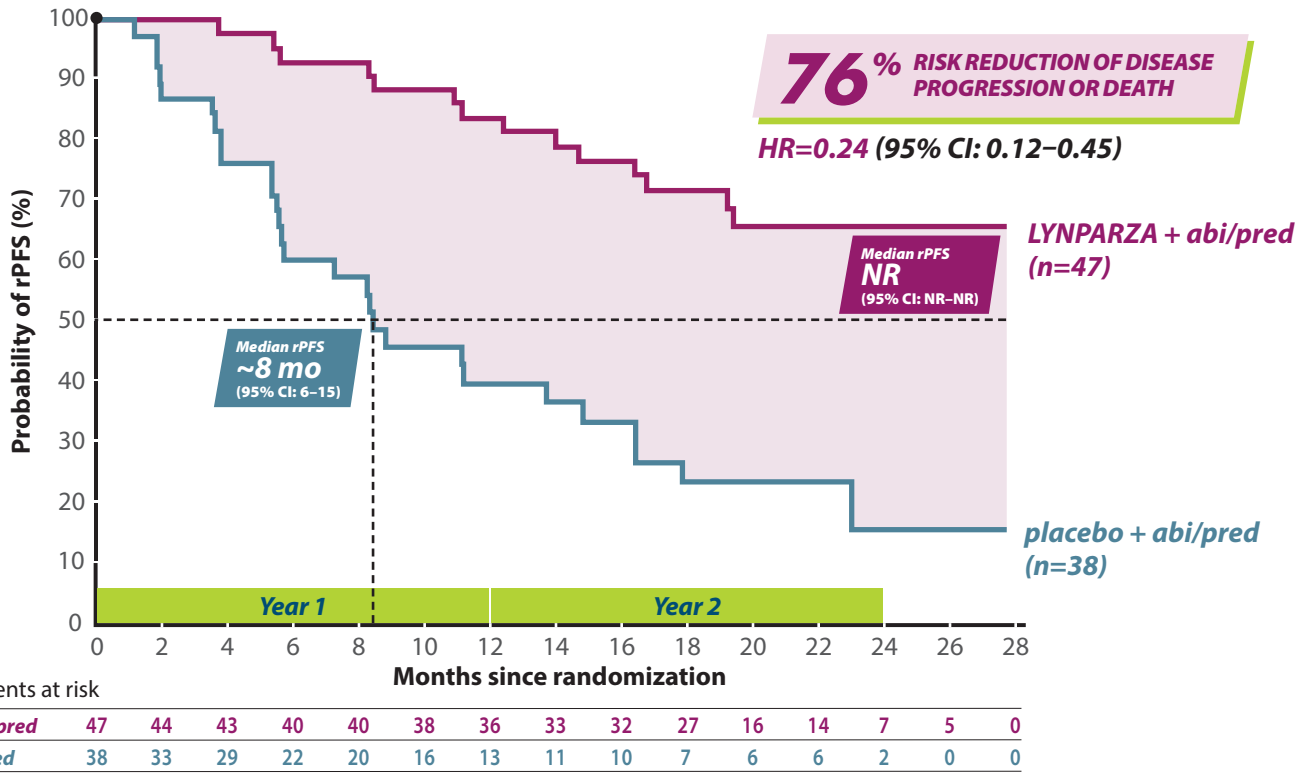
Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA/abiraterone with a difference of ≥5% compared to placebo for **PROpel** were: anemia (48%), fatigue (including asthenia) (38%), nausea (30%), diarrhea (19%), decreased appetite (16%), lymphopenia (14%), dizziness (14%), and abdominal pain (13%).

Most common laboratory abnormalities (Grades 1-4) in ≥20% of patients who received LYNPARZA/abiraterone for **PROpel** were: decrease in hemoglobin (97%), decrease in lymphocytes (70%), decrease in platelets (23%), and decrease in absolute neutrophil count (23%).

FDA approval of LYNPARZA + abi/pred was based on an exploratory BRCAm subgroup

LYNPARZA + abi/pred demonstrated improvement in rPFS vs placebo + abi/pred in patients with BRCAm mCRPC[1,5]

rPFS BY INVESTIGATOR ASSESSMENT IN EXPLORATORY *BRCA*m SUBGROUP



Number of patients at risk

LYNPARZA + abi/pred	47	44	43	40	40	38	36	33	32	27	16	14	7	5	0
placebo + abi/pred	38	33	29	22	20	16	13	11	10	7	6	6	2	0	0

***BRCA*m subgroup (n=85)**
rPFS events, n (%): 14/47 (30) with LYNPARZA + abi/pred and 28/38 (74) with placebo + abi/pred
- Results from the BICR assessment were consistent with the investigator-assessed rPFS results

OS analysis: 70% reduction in risk of death (HR=0.30 [95% CI: 0.15–0.59]) for LYNPARZA + abi/pred vs placebo + abi/pred. OS events, n (%): 13/47 (28) and 25/38 (66), respectively

*BRCA*m status was not a stratification factor in PROpel, and analysis was not controlled for Type 1 error

ITT population (n=796)
Statistically significant improvement in rPFS* was observed for LYNPARZA + abi/pred compared with placebo + abi/pred. OS for LYNPARZA + abi/pred compared to placebo + abi/pred did not reach statistical significance in the ITT population

Patients without an identified *BRCA*m (n=711)
Results from exploratory analyses in this subgroup (rPFS: HR=0.77 [95% CI: 0.63–0.96] and OS: HR=0.92 [95% CI: 0.74–1.14]) indicated that the improvement in the ITT population was primarily attributed to the results seen in the *BRCA*m subgroup

IMPORTANT SAFETY INFORMATION (Cont'd)

DRUG INTERACTIONS

Anticancer Agents: Clinical studies of LYNPARZA with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

CYP3A Inhibitors: Avoid coadministration of strong or moderate CYP3A inhibitors when using LYNPARZA. If a strong or moderate CYP3A inhibitor must be coadministered, reduce the dose of LYNPARZA. Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid coadministration of strong or moderate CYP3A inducers when using LYNPARZA.

USE IN SPECIFIC POPULATIONS

Lactation: No data are available regarding the presence of olaparib in human milk, its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise a lactating woman not to breastfeed during treatment with LYNPARZA and for 1 month after receiving the final dose.

Pediatric Use: The safety and efficacy of LYNPARZA have not been established in pediatric patients.

Hepatic Impairment: No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C).

Renal Impairment: No dosage modification is recommended in patients with mild renal impairment (CLcr 51-80 mL/min estimated by Cockcroft-Gault). In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the dose of LYNPARZA to 200 mg twice daily. There are no data in patients with severe renal impairment or end-stage renal disease (CLcr ≤30 mL/min).

Please see accompanying Brief Summary of Prescribing Information on the following pages.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Choose LYNPARZA + abi/pred as initial therapy for BRCAm mCRPC to help give your patients more time without disease progression

References: 1. LYNPARZA® (olaparib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. **2.** Rubraca® (rucaparib) [prescribing information]. Boulder, CO: Clovis Oncology, Inc.; 2022. **3.** Talzenna® (talazoparib) [prescribing information]. New York, NY: Pfizer Inc.; 2021. **4.** Zejula® (niraparib) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; 2023. **5.** Clarke NW, Armstrong AJ, Thiery-Vuillemin A, et al. Abiraterone and olaparib for metastatic castration-resistant prostate cancer. *NEJM Evid*. Published online June 3, 2022. doi:10.1056/EVIDoa2200043

abi/pred=abiraterone plus prednisone or prednisolone; BICR=blinded independent central review; BID=twice daily; *BRCA*m=*BRCA*-mutated or *BRCA* mutation; CI=confidence interval; ctDNA=circulating tumor DNA; GnRH=gonadotropin-releasing hormone; HR=hazard ratio; HRR=homologous recombination repair; ITT=intent-to-treat; mCRPC=metastatic castration-resistant prostate cancer; mHSPC=metastatic hormone-sensitive prostate cancer; NGS=next-generation sequencing; NR=not reached; OS=overall survival; PARPi=poly (ADP-ribose) polymerase inhibitor; PCWG3=Prostate Cancer Working Group 3; QD=once daily; RECIST=Response Evaluation Criteria in Solid Tumors; rPFS=radiological progression-free survival.

LYNPARZAprhcp.com to explore additional data from the PROpel trial

MERCK AstraZeneca

LYNPARZA® (olaparib) tablets, for oral use

Initial U.S. Approval: 2014

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

INDICATIONS AND USAGE

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer

Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza *[see Dosage and Administration (2.1) in the full Prescribing Information]*.

Treatment of *BRCA*-mutated Metastatic Castration-Resistant Prostate Cancer in Combination with Abiraterone and Prednisone or Prednisolone

Lynparza is indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious *BRCA*-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza *[see Dosage and Administration (2.1) in the full Prescribing Information]*.

DOSAGE AND ADMINISTRATION

Patient Selection

Information on FDA-approved tests for the detection of genetic mutations is available at http://www.fda.gov/companiondiagnostics.

Select patients for treatment with Lynparza based on the presence of deleterious or suspected deleterious HRR gene mutations, including *BRCA* mutations, or genomic instability based on the indication, biomarker, and sample type (Table 1).

Table 1 Biomarker Testing for Patient Selection*

Indication	Biomarker	Sample type		
		Tumor	Blood	Plasma (ctDNA)
Germline or somatic HRR gene-mutated metastatic castration-resistant prostate cancer	*ATM*m, *BRCA1*m, *BRCA2*m, *BARD1*m, *BRIP1*m, *CDK12*m, *CHEK1*m, *CHEK2*m, *FANCL*m, *PALB2*m, *RAD51B*m, *RAD51C*m, *RAD51D*m, *RAD54L*m	X		
	g*BRCA1*m, g*BRCA2*m		X	
	*ATM*m, *BRCA1*m, *BRCA2*m			X
BRCA-mutated metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone or prednisolone	*BRCA1*m, *BRCA2*m	X	X	X

* Where testing fails or tissue sample is unavailable/insufficient, or when germline testing is negative, consider using an alternative test, if available.

Recommended Dosage

The recommended dosage of Lynparza is 300 mg taken orally twice daily, with or without food.

If a patient misses a dose of Lynparza, instruct patient to take their next dose at its scheduled time. Instruct patients to swallow tablets whole. Do not chew, crush, dissolve, or divide tablet.

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer

Continue treatment until disease progression or unacceptable toxicity for:

- HRR gene-mutated metastatic castration-resistant prostate cancer

BRCA-mutated Metastatic Castration-Resistant Prostate Cancer in Combination with Abiraterone and Prednisone or Prednisolone

Continue treatment until disease progression or unacceptable toxicity.

When used with Lynparza, the recommended dose of abiraterone is 1000 mg taken orally once daily. Abiraterone should be given in combination with prednisone or prednisolone 5 mg orally twice daily. Refer to the Prescribing Information for abiraterone for dosing information.

Patients with mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

Dosage Modifications for Adverse Reactions

To manage adverse reactions, consider interruption of treatment or dose reduction. The recommended dose reduction is 250 mg taken twice daily.

If a further dose reduction is required, then reduce to 200 mg taken twice daily.

Dosage Modifications for Concomitant Use with Strong or Moderate CYP3A Inhibitors

Avoid concomitant use of strong or moderate CYP3A inhibitors with Lynparza.

If concomitant use cannot be avoided, reduce Lynparza dosage to:

- 100 mg twice daily when used concomitantly with a strong CYP3A inhibitor.
- 150 mg twice daily when used concomitantly with a moderate CYP3A inhibitor.

After the inhibitor has been discontinued for 3 to 5 elimination half-lives, resume the Lynparza dose taken prior to initiating the CYP3A inhibitor *[see Drug Interactions (7.2) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Dosage Modifications for Renal Impairment

Moderate Renal Impairment

In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the Lynparza dosage to 200 mg orally twice daily *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia

Myelodysplastic syndrome (MDS)/Acute Myeloid Leukemia (AML) has occurred in patients treated with Lynparza and some cases were fatal.

In clinical studies enrolling 2901 patients with various cancers who received Lynparza as a single agent *[see Adverse Reactions (6.1) in the full Prescribing Information]*, the cumulative incidence of MDS/AML was approximately 1.5% (43/2901). Of these, 51% (22/43) had a fatal outcome. The median duration of therapy with Lynparza in patients who developed MDS/AML was 2 years (range: < 6 months to > 10 years). All of these patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

Do not start Lynparza until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt Lynparza and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Lynparza.

Pneumonitis

In clinical studies enrolling 2901 patients with various cancers who received Lynparza as a single agent *[see Adverse Reactions (6.1) in the full Prescribing Information]*, the incidence of pneumonitis, including fatal cases, was 0.8% (24/2901). If patients present with new or worsening respiratory symptoms such as dyspnea, cough and fever, or a radiological abnormality occurs, interrupt Lynparza treatment and promptly assess the source of the symptoms. If pneumonitis is confirmed, discontinue Lynparza treatment and treat the patient appropriately.

Venous Thromboembolism

Venous thromboembolism (VTE), including severe or fatal pulmonary embolism (PE), occurred in patients treated with Lynparza *[see Adverse Reactions (6.1) in the full Prescribing Information]*.

In the combined data of two randomized, placebo-controlled clinical studies (PROfound and PROpel) in patients with metastatic castration-resistant prostate cancer (N=1180), VTE occurred in 8% of patients who received Lynparza, including pulmonary embolism in 6%. In the control arms, VTE occurred in 2.5% including pulmonary embolism in 1.5%.

Monitor patients for clinical signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Embryo-Fetal Toxicity

Lynparza can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. In an animal reproduction study, administration of olaparib to pregnant rats during the period of organogenesis caused teratogenicity and embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 300 mg twice daily. Apprise pregnant women of the potential hazard to a fetus and the potential risk for loss of the pregnancy. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Lynparza. Based on findings from genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of Lynparza *[see Use in Specific Populations (8.1, 8.3) in the full Prescribing Information]*.

ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the labeling:

- Myelodysplastic Syndrome/Acute Myeloid Leukemia *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Pneumonitis *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Venous Thromboembolism *[see Warnings and Precautions (5.3) in the full Prescribing Information]*

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Unless otherwise specified, the data described in the WARNINGS AND PRECAUTIONS reflect exposure to Lynparza as a single agent in 2901 patients; 2135 patients with exposure to 300 mg twice daily tablet dose including five controlled, randomized, trials (SOLO-1, SOLO-2, OlympiAD, POLO, and PROfound) and to 400 mg twice daily capsule dose in 766 patients in other trials that were pooled to conduct safety analyses. In addition to the 2901 patients, certain subsections in the WARNINGS AND PRECAUTIONS include adverse reactions observed with exposure to Lynparza with abiraterone (n=398) in PROpel. All patients with metastatic castration resistant prostate cancer received concomitant ADT or previous bilateral orchiectomy.

In the pooled safety population, 56% of patients were exposed for 6 months or longer and 28% were exposed for greater than one year in the Lynparza group.

In this pooled safety population, the most common adverse reactions in ≥10% of patients were nausea (60%), fatigue (55%), anemia (36%), vomiting (32%), diarrhea (24%), decreased appetite (22%), headache (16%), dysgeusia (15%), cough (15%), neutropenia (14%), dyspnea (14%), dizziness (12%), dyspepsia (12%), leukopenia (11%), and thrombocytopenia (10%).

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer

PROfound

The safety of Lynparza as monotherapy was evaluated in patients with mCRPC and HRR gene mutations who have progressed following prior treatment with enzalutamide or abiraterone in PROfound *[see Clinical Studies (14.7) in the full Prescribing Information]*. This study was a randomized, open-label, multi-center study in which 386 patients received either Lynparza tablets 300 mg orally twice daily (n=256) or investigator's choice of enzalutamide or abiraterone acetate (n=130) until disease progression or unacceptable toxicity. Among patients receiving Lynparza, 62% were exposed for 6 months or longer and 20% were exposed for greater than one year.

Fatal adverse reactions occurred in 4% of patients treated with Lynparza. These included pneumonia (1.2%), cardiopulmonary failure (0.4%), aspiration pneumonia (0.4%), intestinal diverticulum (0.4%), septic shock (0.4%), Budd-Chiari Syndrome (0.4%), sudden death (0.4%), and acute cardiac failure (0.4%).

Serious adverse reactions occurred in 36% of patients receiving Lynparza. The most frequent serious adverse reactions (≥2%) were anemia (9%), pneumonia (4%), pulmonary embolism (2%), fatigue/asthenia (2%), and urinary tract infection (2%).

Dose interruptions due to an adverse reaction of any grade occurred in 45% of patients receiving Lynparza; dose reductions due to an adverse reaction occurred in 22% of Lynparza patients. The most frequent adverse reactions leading to dose interruption of Lynparza were anemia (25%) and thrombocytopenia (6%) and the most frequent adverse reaction leading to reduction of Lynparza was anemia (16%). Discontinuation due to adverse reactions occurred in 18% of Lynparza. The adverse reaction that most frequently led to discontinuation of Lynparza was anemia (7%).

Tables 16 and 17 summarize the adverse reactions and laboratory abnormalities, respectively, in patients in PROfound.

Table 16 Adverse Reactions* Reported in ≥10% of Patients in PROfound

Adverse Reactions	Lynparza tablets n=256		Enzalutamide or abiraterone n=130	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Blood and lymphatic disorders				
Anemia†	46	21	15	5
Thrombocytopenia‡	12	4	3	0
Gastrointestinal disorders				
Nausea	41	1	19	0
Diarrhea	21	1	7	0
Vomiting	18	2	12	1
General disorders and administration site conditions				
Fatigue (including asthenia)	41	3	32	5
Metabolism and nutrition disorders				
Decreased appetite	30	1	18	1
Respiratory, thoracic, and mediastinal disorders				
Cough	11	0	2	0
Dyspnea	10	2	3	0

* Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.
† Includes anemia and hemoglobin decreased.
‡ Includes platelet count decreased and thrombocytopenia.

Clinically relevant adverse reactions that occurred in <10% of patients receiving Lynparza were neutropenia (9%), VTE (7%), dizziness (7%), dysgeusia (7%), dyspepsia (7%), headache (6%), pneumonia (5%), stomatitis (5%), rash (4%), blood creatinine increase (4%), pneumonitis (2%), upper abdominal pain (2%), and hypersensitivity (1%).

Table 17 Laboratory Abnormalities Reported in ≥25% of Patients in PROfound

Laboratory Parameter*	Lynparza tablets n†= 256		Enzalutamide or abiraterone n†=130	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Decrease in hemoglobin	98	13	73	4
Decrease in lymphocytes	62	23	34	13
Decrease in leukocytes	53	4	21	0
Decrease in absolute neutrophil count	34	3	9	0

* Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.
† This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter.

Treatment of *BRCA*-mutated Metastatic Castration-Resistant Prostate Cancer in Combination with Abiraterone and Prednisone or Prednisolone

PROpel

The safety of Lynparza in combination with abiraterone and prednisone or prednisolone for the treatment of patients in the first-line mCRPC setting was investigated in PROpel *[see Clinical Studies (14.8) in the full Prescribing Information]*. Patients were randomized to receive either Lynparza tablets 300 mg orally twice daily plus abiraterone tablets 1000 mg once daily (Lynparza/abiraterone) (n=398), or placebo plus abiraterone 1000 mg once daily (placebo/abiraterone) (n=396) until disease progression or unacceptable toxicity. Patients in both arms also received either prednisone or prednisolone 5 mg twice daily.

Fatal adverse reactions occurred in 6% of patients, including COVID-19 (3%) and pneumonias (0.5%).

Serious adverse reactions occurred in 39% of patients. Serious adverse reactions reported in > 2% of patients included anemia (6%), COVID-19 (6%), pneumonia (4.5%), pulmonary embolism (3.5%), and urinary tract infection (3%).

Permanent discontinuation of Lynparza due to adverse reactions occurred in 16% of patients treated in the Lynparza with abiraterone arm. The most common adverse reactions which resulted in permanent discontinuation of Lynparza were anemia (4.3%) and pneumonia (1.5%).

Dosage interruption of Lynparza due to adverse reactions occurred in 48% of patients treated in the Lynparza with abiraterone arm. The most common (>2%) adverse reactions requiring dosage interruption of Lynparza were anemia (16%), COVID-19 (6%) fatigue (3.5%), nausea (2.8%), pulmonary embolism (2.3%), and diarrhea (2.3%).

Dose reduction of Lynparza due to adverse reactions occurred in 21% of patients treated in the Lynparza with abiraterone arm. The most common (>2%) adverse reactions requiring dosage reductions of Lynparza were anemia (11%) and fatigue (2.5%).

The most common adverse reactions (≥10%) in patients who received Lynparza/abiraterone were anemia (48%), fatigue (38%), nausea (30%), diarrhea (19%), decreased appetite (16%), lymphopenia (14%), abdominal pain (13%), and dizziness (14%).

Tables 18 and 19 summarize adverse reactions and laboratory abnormalities in PROpel, respectively.

Table 18 Adverse Reactions (≥10%) in Patients Who Received Lynparza (with a Difference of ≥5% Compared to Placebo) in PROpel

Adverse Reactions*	Lynparza/abiraterone n=398		Placebo/abiraterone n=396	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Blood and Lymphatic Disorders				
Anemia†	48	16	18	3.3
Lymphopenia‡	14	5	6	1.8
General Disorders and Administration Site Conditions				
Fatigue (including asthenia)	38	2.3	30	1.5
Gastrointestinal Disorders				
Nausea	30	0.3	14	0.3
Diarrhea	19	1	10	0.3
Abdominal pain$^{\alpha}$	13	0	7	0.5
Metabolism and nutrition disorders				
Decreased appetite	16	1	7	0
Nervous System Disorders				
Dizziness$^{\beta}$	14	0.3	7	0

* Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.
† Includes anemia, anemia macrocytic, and red blood cell count decreased
‡ Includes lymphocyte count decreased and lymphopenia
$^{\alpha}$ Includes abdominal discomfort, abdominal pain, abdominal pain upper, and abdominal pain lower
$^{\beta}$ Includes dizziness and vertigo.

Clinically relevant adverse reactions that occurred in <10% for patients receiving Lynparza plus abiraterone were headache (9%), VTE (8%), rash (7%), dysgeusia (6%), acute kidney injury (3%), and stomatitis (2.5%).

Table 19 Selected Laboratory Abnormalities Reported in ≥20% of Patients in PROpel

Laboratory Parameter	Lynparza/abiraterone n=398†		Placebo/abiraterone n=396†	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Decrease in hemoglobin	97	12	81	1.3
Decrease in lymphocytes	70	23	49	11
Decrease in platelets	23	1.2	20	0.3
Decrease in absolute neutrophil count	23	5	6	0

† This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Lynparza. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders: Hypersensitivity including angioedema.

Skin and subcutaneous tissue disorders: Erythema nodosum, rash, dermatitis.

DRUG INTERACTIONS

Use with Anticancer Agents

Clinical studies of Lynparza with other myelosuppressive anticancer agents, including DNA damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

Effect of Other Drugs on Lynparza

Strong and Moderate CYP3A Inhibitors

Coadministration of CYP3A inhibitors can increase olaparib concentrations, which may increase the risk for adverse reactions *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Avoid coadministration of strong or moderate CYP3A inhibitors. If the strong or moderate inhibitor must be coadministered, reduce the dose of Lynparza *[see Dosage and Administration (2.4) in the full Prescribing Information]*.

Strong and Moderate CYP3A Inducers

Concomitant use with a strong or moderate CYP3A inducer decreased olaparib exposure, which may reduce Lynparza efficacy *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Avoid coadministration of strong or moderate CYP3A inducers.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals and its mechanism of action *[see Clinical Pharmacology (12.1) in the full Prescribing Information]*, Lynparza can cause fetal harm when administered to a pregnant woman. There are no available data on Lynparza use in pregnant women to inform the drug-associated risk. In an animal reproduction study, the administration of olaparib to pregnant rats during the period of organogenesis caused teratogenicity and embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 300 mg twice daily *(see Data)*. Apprise pregnant women of the potential hazard to the fetus and the potential risk for loss of the pregnancy.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. The estimated background risk in the U.S. general population of major birth defects is 2-4%; and the risk for spontaneous abortion is approximately 15-20% in clinically recognized pregnancies.

Data

Animal Data

In a fertility and early embryonic development study in female rats, olaparib was administered orally for 14 days before mating through to Day 6 of pregnancy, which resulted in increased post-implantation loss at a dose level of 15 mg/kg/day (with maternal systemic exposures approximately 7% of the human exposure ($AUC_{0\text{-}24h}$) at the recommended dose).

In an embryo-fetal development study, pregnant rats received oral doses of 0.05 and 0.5 mg/kg/day olaparib during the period of organogenesis. A dose of 0.5 mg/kg/day (with maternal systemic exposures approximately 0.18% of human exposure ($AUC_{0\text{-}24h}$) at the recommended dose) caused embryo-fetal toxicities including increased post-implantation loss and major malformations of the eyes (anophthalmia, microphthalmia), vertebrae/ribs (extra rib or ossification center; fused or absent neural arches, ribs, and sternebrae), skull (fused exoccipital), and diaphragm (hernia). Additional abnormalities or variants included incomplete or absent ossification (vertebrae/sternebrae, ribs, limbs) and other findings in the vertebrae/sternebrae, pelvic girdle, lung, thymus, liver, ureter, and umbilical artery. Some findings noted above in the eyes, ribs, and ureter were observed at a dose of 0.05 mg/kg/day olaparib at lower incidence.

Lactation

Risk Summary

No data are available regarding the presence of olaparib in human milk, or on its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infants from Lynparza, advise a lactating woman not to breastfeed during treatment with Lynparza and for one month after receiving the last dose.

Females and Males of Reproductive Potential

Lynparza can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1) in the full Prescribing Information]*.

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating treatment with Lynparza.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with Lynparza and for 6 months following the last dose.

Males

Based on findings in genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of Lynparza. Advise male patients not to donate sperm during therapy and for 3 months following the last dose of Lynparza *[see Use in Specific Populations (8.1) and Nonclinical Toxicology (13.1) in the full Prescribing Information]*.

Pediatric Use

Safety and effectiveness of Lynparza have not been established in pediatric patients.

Geriatric Use

Of the 2901 patients with advanced solid tumors who received Lynparza as a single agent, 680 (23%) patients were aged ≥65 years, and this included 206 (7%) patients who were aged ≥75 years. Thirteen (0.4%) patients were aged ≥85 years.

Of the 535 patients with advanced solid tumors who received Lynparza tablets 300 mg orally twice daily in combination with bevacizumab (PAOLA-1), 204 (38%) patients were aged ≥65 years, and this included 31 (6%) patients who were aged ≥75 years.

Of the 398 patients with advanced solid tumors who received Lynparza tablets 300 mg orally twice daily in combination with abiraterone and prednisone or prednisolone (PROpel), 268 (67%) patients were aged ≥65 years, and this included 95 (24%) patients who were aged ≥75 years.

No overall differences in the safety or effectiveness of Lynparza were observed between these patients and younger patients.

Renal Impairment

No dosage modification is recommended in patients with mild renal impairment (CLcr 51 to 80 mL/min estimated by Cockcroft-Gault). Reduce Lynparza dosage to 200 mg twice daily in patients with moderate renal impairment (CLcr 31 to 50 mL/min) *[see Dosage and Administration (2.5) in the full Prescribing Information]*. There are no data in patients with severe renal impairment or end-stage disease (CLcr ≤30 mL/min) *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Hepatic Impairment

No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C) *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

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HUMANITARIAN

The AUA's Ongoing Commitment to Our Global Humanitarian Mission

David F. Penson, MD, MPH
Secretary, AUA

The AUA is committed to improving urologic and public health around the world. The collective humanitarian work of the AUA and the Urology Care Foundation™ (UCF) continues to elevate urological health care across the world, and this important issue of *AUANews* is a showcase of these efforts. Thank you to Dr Stacy Tanaka for publishing this first humanitarian focus issue, hopefully the first of many features of this important work in *AUANews*.

This issue wouldn't have happened without the hard work and dedication of Dr Harris Nagler and Guest Editor Dr Joseph Smith. These efforts to improve global health continue to make the world a better place for all. Although the AUA and UCF support many global humanitarian projects, I have chosen to focus on 2 of our most critical humanitarian efforts: AUA support of urologic educational training in Haiti through the Global Philanthropic Committee (GPC) and our Humanitarian Grants Program.

In 2010, Dr Robert Flanigan, then the AUA secretary, helped spearhead the creation of the GPC, a partnership of the AUA, the European Association of Urology, and the Société Internationale d'Urologie, to provide support to humanitarian efforts in global areas of need. In 2016, the International Continence Society joined the collaboration. In a 2021 *European Urology Today* article, Dr John Denstedt noted that "The GPC is a way for urology organizations to pool their collective resources to fund larger humanitarian projects in urology. It is a way for the largest urological societies in the world to collaborate and to focus on a common goal of advancing urology in underserved areas."[1] Through the GPC, the AUA has supported urologic educational training in Haiti. Specifically, the AUA has supported the work of a dedicated urology nurse at the Hôpital Saint François de Sale in Port-au-Prince, Haiti. This nurse manages and oversees all of the urological equipment at the hospital and teaches and assists local clinicians to deliver critical urologic care to those most in need. In addition, the AUA and the GPC have worked with industry supporters and individual donors to send thousands of dollars' worth of equipment and supplies to Haiti. Finally, the AUA and GPC have worked closely with Dr Angelo Gousse and the Global Association for the Support of Haitian Urology to support ongoing urologic education, including several seminars, workshops, and conferences for local urologists in Port-au-Prince.

> "In addition, the AUA and the GPC have worked with industry supporters and individual donors to send thousands of dollars' worth of equipment and supplies to Haiti."

> "This issue wouldn't have happened without the hard work and dedication of Dr Harris Nagler and Guest Editor Dr Joseph Smith."

Figure. QR code to access the recording of the Urology Care Foundation podcast "From Healing to Hope: Urologists Share Their Passion for Changing Lives Around the World," featuring Urology Care Foundation™ winners Drs Rajiv K. Singal and Dana Weiss.

On a different note, the UCF's Humanitarian Grants Program has focused on supporting the individual efforts of AUA members to improve global health. This year, 6 AUA members received grants for their affiliated work with nonprofit organizations both within and outside the United States. The stories of these winners are compelling and motivational. Lee Ann Richter, MD, of Georgetown University School of Medicine, serves on the Board of the International Organization for Women and Development. She spends 2 weeks a year in Rwanda, providing fistula repair–related evaluations and operations. Kymora Scotland, MD, of the University of California, Los Angeles, plans to partner with Gold Standard Urology to host screening events for a wide range of urological conditions in south Los Angeles. Rajiv K. Singal, MD, FRCSC, of Michael Garron Hospital in Toronto, is working to create resources for sustainable urological health care in Malawi. Samit Sunny Roy, MD, MSPH, of the University of Tennessee, will provide urological surgery training and postoperative care during an upcoming stay at the Sadhbhavna Trust Hospital, Kalsar, Bhavnager, Mahua, Gujarat, India. Suzette Sutherland, MD, of the University of Washington, regularly volunteers her expertise in Dakar, Senegal, and will travel there again in fall 2023 with IVUMed (International Volunteers in Urology) to evaluate patients with stress urinary incontinence, emphasizing the use of low-risk, minimally invasive treatments. Dana Weiss of the Children's Hospital of Philadelphia is a 16-year volunteer at the Civil Hospital Amdavd in Ahmedabad, Gujarat, India, where she has provided direct care to patients with bladder exstrophy.

> "This year, 6 AUA members received grants for their affiliated work with nonprofit organizations both within and outside the United States."

As part of this focus issue, the Urology Care Foundation recorded a podcast with 2 of the 7 UCF win-ners: Drs Singal, Smith, and Weiss (Figure). I encourage you to take the time to learn more about their goals and missions and what they have learned from their one-of-a-kind experiences. ■

1. Long-term and sustained improvements is the goal. *European Urology Today*. September 21, 2021:43.

HUMANITARIAN

Introduction From the Guest Editor

Joseph A. Smith Jr, MD
Vanderbilt University, Nashville, Tennessee

A humanitarian is defined in the dictionary as "a person concerned with or seeking to promote human welfare." Such a broad portrayal obviously encompasses many activities and passions. In fact, much of the day-to-day activity of a physician could be categorized under that delineation. There are amongst our colleagues, though, individuals whose dedication, effort, and selflessness transcend norms and can be recognized as truly altruistic.

This issue of *AUANews* captures briefly the story of some of those individuals. Although few would contest an overarching label of humanitarian for their efforts, each is distinguished by different circumstances, opportunities, and accomplishments. The stories range from those of Dr Denis Mukwege (Figure), a Nobel Peace Prize winner on the front lines of a conflict region in the Democratic Republic of the Congo, to individuals devoted to improving care for the disadvantaged or marginalized in their own community. There is a preponderance of articles about international work, but that doesn't imply that there aren't opportunities for the best of humanitarian work in virtually every neighborhood. One doesn't have to travel halfway around the world to find people in need.

Particularly inspiring are the experiences of individuals who have devoted their entire adult lives to helping others. Dr Kenneth Johnson describes life as a Jesuit priest and surgeon assigned to an unexpected lifelong presence in Zambia and Malawi. Other responsibilities including family commitments don't permit such a role for others, but enormous contributions can also be achieved through short-term surgical missions, especially those devoted to training local surgeons.

Most students entering medical school are at least partially motivated by heartfelt humanitarian intent. Somewhere along the way, though, that seems to get partially extinguished, or at least not visibly manifest, in some. Of course, the most genuine of charitable efforts may not be obvious but can include work within one's church, schools, or community programs. This issue of *AUANews* does, though, focus mainly on humanitarian ventures related to medicine and surgery.

> "Most students entering medical school are at least partially motivated by heartfelt humanitarian intent."

Figure. Dr Denis Mukwege and Dr Joseph Smith at Panzi Hospital, Democratic Republic of Congo.

Urologic surgeons have particular skills and experience which can make dramatic differences in their patients' lives and which can readily translate into benevolent missions. A goal of publishing these stories is not only to motivate humanitarian works, but also to provide a roadmap for the variety of ways in which they can appear.

Connection with an established organization devoted to humanitarian work is a potential entry point for those wondering how to get started. With that intent, programs associated with the Urology Care Foundation™, IVUmed, the Pan African Association of Christian Surgeons, and others are used as examples of what can occur. Some are faith based, others associated with professional organizations, and additional ones are secular, independent charitable ventures. All have a common theme of selfless devotion to others and fulfill the loftiest ideals of humanitarianism. The definition of the word may be broad, but the mission it entails for surgeons is distinct. It is my hope as guest editor of this issue that readers are inspired by the work of their colleagues and that it furthers their own humanitarian spirit, regardless of how that is manifest. ■

HUMANITARIAN

Panzi Hospital

Denis Mukwege, MD
Panzi Hospital, Bukavu, Democratic Republic of the Congo
Nobel Peace Prize winner 2018

Raha Maroy, MD
Panzi Hospital, Bukavu, Democratic Republic of the Congo

Panzi Hospital was founded in 1999, in a region devastated by armed conflicts and wars. The main goal for founding the hospital was to safeguard women's lives and ensure proper delivery of babies. Unfortunately, our very first patient came with extreme wounds from sexual violence. She was shot in her genitals after enduring a brutal rape.

The flow of patient-survivors of sexual violence kept growing since then.

We had to adapt and develop techniques to deal with and treat those new types of wounds. To this date, we have performed over 80,000 surgeries of different categories, to repair genital damages done to women. We had to develop special techniques for fistula treatment, prolapses, and the care for rape victims under the age of 5.

We now train doctors from

→ Continued on page 9

PANZI HOSPITAL

→ Continued from page 8

> "We had to adapt and develop techniques to deal with and treat those new types of wounds. To this date, we have performed over 80,000 surgeries of different categories, to repair genital damages done to women."

other regions within the Democratic Republic of the Congo (DRC) or other countries in the treatments we have developed and specialized in at Panzi. We have sent teams to treat patients and train local doctors in Guinea, the Central African Republic, and Ukraine, among others. In 2022, we inaugurated the African Minimally Invasive Surgery Institute facility within the Panzi Hospital to further our improvement in surgery performance.

In the meantime, we continue our work as a regular hospital, treating different types of patients and illnesses. With a maternity ward that averages 3500 deliveries per year, our initial goal to strive for reducing maternal death has brought encouraging results. We currently have a 99.1% live birth rate and strongly work to continue to increase it.

Guest Editor's Note

Joseph A. Smith Jr, MD
Director of Global Surgery
Vanderbilt University, Nashville, Tennessee

Dr Mukwege, the 2018 Nobel Peace Prize winner, understates his own accomplishments and his lifelong commitment to humanitarian work. His efforts have come with substantial risk to his own safety, but he has been undeterred in ministering to the women who are victims of the ongoing violence in the eastern regions of the DRC.[1,2] The remarkable contribution of Panzi Hospital to the health and well-being of women in the DRC is facilitated by the support and dedication of the team he has put together.[3] I have had the opportunity to work with Dr Mukwege and his colleagues on several occasions at Panzi Hospital and can attest to not only their skills but also their compassion and commitment. Their efforts present an example for readers of *AUANews* to learn what can be achieved with selfless dedication to humanitarian causes. ■

1. Mukwege DM, Mohamed-Ahmed O, Fitchett JR. Rape as a strategy of war in the Democratic Republic of the Congo. *Int Health.* 2010;2(3):163-164.
2. Mukwege DM, Nangini C. Rape with extreme sexual violence: the new pathology in South Kivu, Democratic Republic of Congo. *PLoS Med.* 2009;6(12):e1000204.
3. Mukwege D. *The Power of Women*. Flatiron Books; 2021.

HUMANITARIAN

How Do We Find the Purpose We Are All Seeking?

Kurt McCammon, MD
Eastern Virginia Medical School, Norfolk
Urology of Virginia, Virginia Beach

We live in a world in which we need to share responsibility. It's easy to say, "It's not my child, not my community, not my world, not my problem." Then there are those who see the need and respond. I consider those people my heroes.
Fred Rogers

Humanitarianism

It's a big word, with a lot of meanings. *Oxford English Dictionary* defines it as "the promotion of human welfare." Why is this important to us? As urologic surgeons, we have a unique skill set that makes a significant impact in the quality of human life, through managing the conditions that affect the urinary and reproductive systems in adults and children. We are privileged by our choice and capacity to study and practice urology. We have personally benefited from the hard work we have committed to, to learn our craft and solve painful, life-threatening, and/or life-altering urologic problems for the benefit of the patients we serve every day in our diverse practice settings.

Humanitarianism isn't asking us to sacrifice ourselves. It doesn't mean we have to travel insurmountable miles or be subjected to threatening situations. It asks us to examine our capacity to give what we can. Everyone benefits when we collaborate sincerely. Honestly, humanitarianism meets us all where we are, whether in our home community's free clinic for a couple of hours a month to care for worthy patients without access to our private services, or in an amazing place for a few weeks over your life's years to connect with and support the development of faculty and trainees to bolster their capacity to better serve their communities. It could also look like a mentoring opportunity to help colleagues in resource-limited settings to conduct and publish research or process improvement that defines appropriate guidelines for urologic patient care in their specific limited setting that matches their resources rather than promoting the unattainable Western guidelines that cannot be universally applied. Maybe you can host students, trainees, or junior faculty from abroad at your hospital for a bidirectional academic experience! The possibilities here are endless, and your specific strengths will guide your path to humanitarian realization.

My journey with humanitarian work began when I was very fortunate to have been asked to go on an IVU (International Volunteers in Urology) trip to Jos, Nigeria, to treat women with vesicovaginal fistulas. This trip not only opened my eyes to the needs and disparity in the world, but also reminded me of my love for medicine and the need to give back. Going on that trip, I felt hopeful I would be able to help some patients. Never did I realize what benefits I would receive. Since then, I have grown and learned so much, not only as a person, but as an educator and a surgeon. There is a large burden of vesicovaginal fistulas in low- and middle-income countries but also a significant number of nongovernmental organizations focused on this. Being trained in urethral reconstruction, I was being asked to do some urethroplasties while there, and what I came to realize was the burden of patients with urethral stricture was also huge with few focused on training others. After going on a few trips a year and working with random surgeons, I realized to make a sustainable difference we needed to focus on centers to create centers of excellence. This has been our focus over the last 8 to 10 years, where we attempt to go back yearly to the same centers working with the same surgeons. Many of these hosts have become some of my and my family's best friends. But not is it only rewarding personally from these friendships and the gratification of seeing our colleagues grow as surgeons, but we have published a paper showing the success rates for urethral reconstruction by the surgeons we work with in Dakar, Senegal, have increased 300%.[1]

Winston Churchill has many quotes that should not appear here, but one we all should live by and likely why many of us went into medicine is, "We make a living by what we get, but we make a life through what we give."

Figure 1. First urethral reconstruction workshop at Black Lion Teaching Hospital with host urologist Abeselom Lemma Gebreamlak.

Figure 2. Urethral reconstruction workshop at San Fernando General Hospital with Jack Zuckerman working with hosts Kirk Goodens and Satyendra Persaud.

Figure 3. Urethral reconstruction workshop at HOGGY Hospital in Dakar, Senegal, with Maahum Haider and host urologist Mohamed Jalloh.

"After going on a few trips a year and working with random surgeons, I realized to make a sustainable difference we needed to focus on centers to create centers of excellence."

In Conclusion

What does humanitarianism mean to you? Every one of us has a unique skill set and perspective to offer. We can't single-handedly save the world, but we can each participate through harnessing the good that is within each of us to support our commitment to our profession in a sustainable way, locally, regionally, and globally. You will make a difference.

Contact me with any questions (mccammka@evms.edu)! ■

1. Haider M, Jalloh M, Yin J, et al. The role of international partnerships in improving urethral reconstruction in low- and middle-income countries. *World J Urol.* 2020;38(12):3003-3011.

HUMANITARIAN

An "Alternative Vacation": A Volunteer Fortnight to a Training Center in Sub-Saharan Africa

John L. Tarpley, MD, FWACS, FACS
Vanderbilt University, Nashville, Tennessee

Erik N. Hansen, MD, MPH, FACS, FCS (ECSA)
Phoenix Children's Hospital, Arizona

For this special Humanitarian Issue of *AUANews*, I will share 2 experiences from my 18 years with feet on the ground in Sub-Saharan Africa (SSA) and an example from Kenya.

During my residency in general surgery, the sum of my formal urology training was a 1-month internship at the Brady Urological Institute in Baltimore. Postresidency, my first position was at the Baptist Medical Centre (BMC), Ogbomoso, Nigeria. I was at BMC for 12 years between 1978 and 1993, with each fourth year back in Baltimore at the Loch Raven VA. In Nigeria, urology was about a fifth of my practice. The most frequent diagnoses were benign prostatic hyperplasia, presenting often in acute retention, urethral stricture from gonococcal urethritis and trauma, prostate cancer, torsion of the cord/testis, but rarely urolithiasis. Fortunately, there was an experienced surgeon at BMC who taught me his way of dealing with many of these–for me–challenges. In the early 1980s, a community urologist from Kerrville, Texas, Dr Theron Hawkins, who passed in 2020, visited my colleague Dr Don Meier and me for 2 weeks. We depended on visitors staying for 2 weeks to help us upscale our practice on many fronts–orthopedics, pediatric surgery, plastic surgery, anesthesia, etc. Dr Hawkins was one of the most important visitors during my 12 years in southwestern Nigeria. We requested that he help us become better at cystoscopy and, hopefully, bring us a rigid urethroscope. During his first 2-week visit, Dr Hawkins observed our practices across many genitourinary fronts, but most importantly for open, transvesical prostatectomy with postop continuous bladder irrigation and van Buren sound or filiform and follower dilatations for most patients with urethral strictures. In the course of that fortnight and a second visit a year later, he reflected on what we might do to improve patient care. He then taught us how to perform a prostatectomy using a Malament suture to eliminate the need for continuous bladder irrigation and how to perform direct vision internal urethrotomy, thus moving the quality of our urologic practice up 2 logs. He even repaired our autoclave! Subsequent to his investment of time and personal expense, we presented our experiences with the Malament technique and with direct vision internal urethrotomy to 2 clinical congresses of the West African College of Surgeons. A publication ensued with 4 of our Nigerian trainees in the authorship along with Dr Hawkins and Dr John D. McConnell: "The outcome of suprapubic prostatectomy: a contemporary series in the developing world".[1] To this day, in many hospitals in West Africa, open prostatectomy with the Malament suture is used to essentially eliminate the need for both continuous irrigation and transfusions.

After 23 years at the Nashville VA (1993-2016) and about 20 years as program director for general surgery, with annual visits to SSA to "water friendships" and take specialist colleagues along to improve skills, my wife and I returned to SSA for an additional 5 years (1 year each in Kenya and Rwanda and 3 years in Botswana). In Kijabe, Kenya, I worked with Dr Erik Hansen, pediatric surgeon at BethanyKids at Kijabe Hospital in the Central Highlands (Figure 1).

Dr Erik Hansen writes:

The vast majority of pediatric urology was outside the scope of my pediatric surgical training in the United States but made up 40% of my practice in Kenya. Like other expat surgeons working in low- and middle-income country hospitals, I had the opportunity to learn to do operations and care for children with conditions that were new to me. I'm indebted to pediatric urologists like Ron Sutherland and Lynn Teague who invested in our patients, the pediatric surgical trainees, and me to advance and improve the urologic care we provided. Through repeated visits to Kijabe and generous gifts of equipment, they graciously and patiently 'taught the trainer' and equipped me and the program so that we could continue to teach the fellows increasingly complex pediatric urology. Their impact is immense, and they have expanded pediatric urologic care through skills and knowledge passed on to pediatric surgical graduates practicing across SSA.

Figure 1. Trainers and trainees (left to right): Dr Erik Hansen, pediatric surgeon; Dr Amon M. Ngongola, consultant pediatric surgeon, University Teaching Hospital, Zambia; Alain Jules Ndibanje, consultant pediatric surgeon, University of Rwanda, Kigali, Rwanda; Dr Yves Mpongo, attending pediatric surgeon, SIM Galmi Hospital, Niger; Dr Ron Sutherland, pediatric urologist, Hawaii.

Figure 2. Genitourinary Team Kijabe 2023: David Muchiri, medical assistant; Dr Irungu Juma, attending urologist; Dr Paul Shu, a visiting G/S resident from Mbingo, Cameroon.

The College of Surgeons of East, Central, and Southern Africa (COSECSA) started in 1999 to address the education of surgeons for the subregion, where there was 1 surgeon per 200,000 persons amongst the 12 countries in COSECSA as of 2017. In Kenya, currently there are approximately 45 urologists for a population of 55 million (1:1,200,000). The University of Nairobi is the only urology residency program in Kenya. Kijabe Hospital, with 2 Kenyan urologists, is launching a residency program in urology (Figure 2).

Figure 3. Dr Jack Barasa, attending urologist and chief of surgery, AIC Kijabe Hospital, Kenya.

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AN "ALTERNATIVE VACATION": A VOLUNTEER FORTNIGHT

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Figure 4. Dr Irungu Juma, attending urologist, AIC Kijabe Hospital, Kenya.

Dr Jack Barasa trained initially as a general surgeon and is chief of surgery at Kijabe (Figure 3). He completed a 2-year urology fellowship in Liverpool, United Kingdom and returned to Kenya. Dr Irungu Juma trained at the Kilimanjaro Christian Medical Centre in Moshi, Tanzania, which has trained urologists for the subregion since the 1970s (Figure 4). With 2 urologists on faculty, the program can be approved by COSECSA and will be part of the capacity-building initiative of the Pan-African Academy of Christian Surgeons (PAACS), a faith-based nongovernmental organization which launched its first program in 1997. The Kijabe genitourinary program will be the first PAACS urology training program. Currently, PAACS has training programs (general surgery, orthopedic surgery, pediatric surgery, anesthesiology, Ob/Gyn, neurosurgery, plastic surgery, and fellowships in head and neck surgery and cardiothoracic surgery) in 19 hospitals spread across 11 countries with 150 residents and fellows.

PAACS and other SSA training programs depend on volunteers to help upscale, broaden, and modernize their curriculum, scope of practice, efficiency, and especially their safety and quality. Nigh every specialty in the broad tent of surgery in SSA needs more providers. Urology is one of the areas needing more providers for male and female adults and children, and those with differences in sex development.

Note: The late Professor John Kwateboi Marmon Quartey of Korle Bu in Accra, Ghana, befriended Dr Meier and me. He taught us his vascularized penile/preputial skin flap open urethroplasty.[2] Learning and teaching were and are bilateral.

Websites for those interested:

Pan-African Academy of Christian Surgeons (https://paacs.net/)

Kenya Association of Urological Surgeons (https://www.kaus.or.ke)

Pan African Urological Surgeon Association (https://pausaafrica.org)

Prof. J.K.M Quartey & Others-My Tribute (modernghana.com)

J Lester Eshleman (1921-2009)-Find a Grave Memorial (https://www.findagrave.com/memorial/33152862/j-lester-eshleman) ■

1. Meier DE, Tarpley JL, Imediegwu OO, et al. The outcome of suprapubic prostatectomy: a contemporary series in the developing world. *Urology*. 1995;46(1):40-44.

2. Quartey JK. One-stage penile/preputial island flap urethroplasty for urethral stricture. *J Urol*. 1985;134(3):474-475.

HUMANITARIAN

The Pan-African Academy of Christian Surgeons Trains Surgeons to Tackle the Problem of Surgical Disease in Africa

Ronald S. Sutherland, MD
Hawaii Pacific Health Medical Group, Honolulu

Imagine having only 1 pediatric surgeon in your city, county, or state of over 4 million people. Worse, that surgeon would be responsible for not only gastrointestinal problems, but also most urological, vascular, thoracic, ENT, plastics, and neurosurgical problems. Overwhelming, right? Such is the problem faced by most of sub-Saharan Africa. That is the burden being addressed by the Pan-African Academy of Christian Surgeons (PAACS), an organization training general surgeons, other specialty surgeons, and anesthesiologists across Africa.

Faced with the enormity of this burden that would outlast them, career missionary surgeons in Africa founded PAACS in 1996 to tackle the problem. Their mission was to train African surgeons who would commit to staying in Africa, mostly in rural locales. The training would take place in mission hospitals across Africa in the form of a 5-year residency. The first surgeon graduated in 2002 from the Bongolo Mission Hospital in Gabon and went to serve in his home country of Madagascar. PAACS programs soon began to multiply, staffed by career missionary and locally trained surgeons, using a contextually relevant curriculum, accredited by Loma Linda University and the College of Surgeons of East, Central and South Africa (COSECSA), and collaboration with the West African College of Surgeons (WACS). Now 20+ years from its beginning, over 142 surgeons have graduated, honored

> "Now 20+ years from its beginning, over 142 surgeons have graduated, honored their commitments to stay in Africa, and are contributing significantly to the health care of an entire continent."

Figure. Author (third from right) with pediatric surgery team at BethanyKids/Kijabe Hospital, with photos of past graduates.

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THE PAN-AFRICAN ACADEMY OF CHRISTIAN SURGEONS TRAINS SURGEONS

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their commitments to stay in Africa, and are contributing significantly to the health care of an entire continent. Their stories are legendary, some of which can be found at the PAACS.net website. Currently, PAACS training programs are in 17 hospitals in 11 countries and comprise 14 general surgery (1 new program next year) and 10 specialty programs. Specialty programs include pediatric surgery, orthopedics, cardiothoracic, neurosurgery, plastic surgery, anesthesia, obstetrics-gynecology, and head-neck surgery.

Notice that urology is absent from the list of specialty programs, but not for long. That is because the need for urologists in Africa is great. PAACS program directors estimate that the number of urology patients which general or pediatric surgeons care for ranges from 30% to 45% of their workload. To address that need, a team of PAACS urologists is investigating the possibility of starting 1 or more urology residency programs in the PAACS model. The first program will likely start in Kenya, alongside one of its general surgery programs. Initially, urology trainees will have completed general surgery training prior to entering a 3-year urology fellowship. This will allow graduates to provide both urology and general surgery staffing at other PAACS surgery training hospitals where general surgery needs are still paramount. Future consideration includes creating a 5-year residency (2 years of general surgery, 3 years of urology), depending on the need of the region where the graduate would serve.

Pediatric urology training has been at the heart of the PAACS Pediatric Surgery Fellowship program, which started in 2005 at BethanyKids/Kijabe Hospital, about an hour north of Nairobi, Kenya. Its curriculum includes an extensive amount of pediatric urology as most pediatric urology in Africa is done by pediatric surgeons. Several pediatric urologists from the US (including this author) have worked with the staff pediatric surgeons at Kijabe to train the fellows in management of congenital urogenital anomalies, trauma, cancer, and infectious/inflammatory diseases. The 3-year fellowship program has graduated 14 pediatric surgeons and is looking to start new programs in other countries as well. The BethanyKids/Kijabe program now includes a 5-year residency (2 years of general surgery, 3 years of pediatric surgery) as well as the 3-year fellowship (Figure).

As programs expand, so too does word of PAACS's reputation for caring and excellence. And the

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> "PAACS program directors estimate that the number of urology patients which general or pediatric surgeons care for ranges from 30% to 45% of their workload."

THE PAN-AFRICAN ACADEMY OF CHRISTIAN SURGEONS TRAINS SURGEONS

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patients come. From everywhere. By foot, cart, scooter, rail, car, or packed minibuses. The volume of urology cases at the training hospitals does not appear to be diminishing, nor does the acuity of these problems. At BethanyKids/Kijabe Hospital, where the pediatric surgeons are now comfortable with most pediatric urology patients, visiting urologists rarely enjoy the luxury of doing a routine hypospadias or other relatively minor problems. Instead, they are greeted with problems like severe stricture disease from pelvic/perineal trauma, redo hypospadias and exstrophy, and other challenging reoperative cases.

> "As programs expand, so too does word of PAACS's reputation for caring and excellence. And the patients come. From everywhere."

These challenges provide wonderful training opportunities not only for the pediatric surgery fellows and residents and the program faculty, but also for visiting specialists who find themselves outside their comfort zones and reliant on the skill and innovation of the faculty surgeons who are deeply committed to training their proteges.

PAACS enjoys its growth and success not only because of the committed career surgical trainers across Africa, but also because of an administrative organization that is highly engaged in providing program oversight and guidance, vision, curriculum development, and financial and spiritual support. A small army of volunteers give time and treasure to support the programs. Visiting faculty find that the time spent at the training sites yields far greater reward for the visitor than the trainees. The life of this surgeon and author has been forever changed by working alongside PAACS surgeons and trainees who are so deeply committed to the vision of caring for the people of Africa. One day soon, urology training programs will also be able to partner in the PAACS's vision for Africa.

For those who want to learn more about opportunities to get involved with PAACS, please see PAACS.net. ■

HUMANITARIAN

Global Humanitarian Work

Gopal Badlani, MD, FACS, FRCS
Wake Forest University, Winston Salem, North Carolina

Generosity is giving more than you can, and pride is taking less than you need.
Khalil Gibran

To serve self first appears to be the guiding principle for most, in all aspects of the life. The transformation to serve the purpose without consideration of "me" takes a conscious effort after a higher learning. It is a refreshing release when an action is without an expectation of return or a goal of self-enhancement.

We are able to do this somewhat in our personal life, perhaps just with our children and spouse. Even there, it is partial as the emotional return is an expectation.

Once we step out of the house, we rarely are able to do something at work or while serving an organization without consideration of me first. These actions are subtle most of the time without an overt desire to do so. At other times it is blatant and in your face. It may be the norm in the political or business dealings, but it is also very prevalent in organized medicine.

There is no formal teaching of this process, and I guess it evolved from the self-preservation instinct. However, it appears to be present in late stages of life, even after significant achievements and glory.

How and when does the "Want" stop and just giving begin?

Giving is not money alone but doing the right thing or action after taking self out. It is difficult and often needs a life coach. When it happens, the inner happiness quotient improves along with the conscious. You collect a different set of wealth, which you carry with yourself at the end.

As an immigrant who has seen both sides of global health (the haves and the have-nots), I had the desire to pursue this path and was fortunate to have spiritual guidance

> "Giving is not money alone but doing the right thing or action after taking self out."

to do more for those in need. Organizations such as IVUmed and JSS (Jeev Sewa Sansthan) carried the heavy load of arrangements, and the team from the US and locals made it possible. There were many colleagues, like Dr Sakti Das, Dr Raju Thomas, Dr Bhushan Khashu, and Dr Amar Singh, as well as residents and fellows who made it possible.

Fistula Care in Africa was in partnership with the International Organization for Women and Development. Barbara and Ira Margolis were godsent people for these women in desperate need.

Facilitating humanitarian missions in urology has been my good fortune through the AUA: the Global Philanthropic Committee, which was a partnership between the AUA, European Association of Urology, and the International Society of Urology, established and supported centers in Dakar, Senegal, as well as Nigeria.

Through the Endourological Society World Endo program, we were able to teach urologists from low- and middle-income countries.

The Urology Care Foundation™ and the 14 humanitarian endowments is an achievement we are very proud of.

> "Bringing all these groups together under one umbrella and matching those in need with those who can help is our latest effort (Urogive.org)."

Bringing all these groups together under one umbrella and matching those in need with those who can help is our latest effort (Urogive.org).

I am mostly addicted to it now and, until I am unable to, will continue on this path. A report of more than 25 years of sustained urological philanthropic effort in India by global urologists through JSS & IVUmed was presented at the AUA Annual Meeting in 2021.[1] ■

1. Badlani G, Das S, Thomas R, Singh A. MP67-17 Report of more than 25 years of sustained urological philanthropic effort in India by global urologist through "Jeev Sewa Sansthan" (JSS) & IVUmed. *J Urol.* 2021;206(Suppl 3):e516.

HUMANITARIAN

Urology Care Foundation™ Humanitarian Initiatives: 3 Years in...and Growing

Harris M. Nagler, MD, FACS
President, Urology Care Foundation™

The Urology Care Foundation™'s (UCF) vision is to be the leader in improving health care for urologic patients worldwide by supporting research, providing patient education, and advancing humanitarian initiatives.

In 2021 the Foundation embarked on a 3-part plan to embed humanitarianism into the Foundation's global vision and mission and to elevate the importance of humanitarianism within urology. The Board of Directors has held steady to this commitment, promulgating how humanitarian efforts are intrinsic to addressing disparities in health care opportunities, access, and care.

Now, 3 years into our humanitarian journey, the Foundation is proud to be recognizing, building, and supporting the efforts of the highly motivated and productive community of urology volunteers.

Humanitarian Recognition Award—Phase 1

The Humanitarian Recognition Award acknowledges individuals who have made outstanding contributions to meeting the needs of the underserved. This award demonstrates to the urologic community that these efforts are important, valued, and worthy of recognition. We are proud to have recognized our first 3 award winners–for decades of service improving the lives of patients in underserved areas across the globe, for passion and excellence in teaching, and building individual and organizational relationships (Table 1).

Humanitarian Grant Program—Phase 2

The UCF Humanitarian Grant Program has generated tremendous momentum. With the shared vision and support of the AUA, Foundation leaders have worked with individuals, organizations, and AUA Sections to establish more than a dozen humanitarian endowments. These endowments provide annual grants to AUA members and their ongoing projects both within and outside the US. Their significant accomplishments are evaluated based on project impact on urologic patient care, educational programming, and efforts to support sustainability. We are pleased to have awarded our first 15 humanitarian grantees (Table 2).

We are excited about the Foundation's support of the humanitarian community and are constantly inspired by the work of AUA volunteers. Reports and testimonials reinforce our desire to work even harder to perpetuate these types of opportunities.

We focused on teaching TURPs (transurethral resection of the prostate) as the current management of most men with urinary retention is a chronic indwelling catheter. One of the patients we cared for had a catheter for the last 2 years and 9 months and left the hospital voiding on his own after his surgery–one of the happiest people on the planet. I'm amazed at the resilience of people in the face of hardships and the incredible opportunity we have as surgeons to change people's lives for the better.
Timothy Schuster

The head doctor of the hospital told us that the Indian culture always emphasizes giving over receiving. Despite our best efforts to give our time, energy, and compassion, I still came away feeling as though we received so much more than we gave.
Alan Yaghoubian

Health Equity Fellowship—Phase 3

Launched in the spring of 2023, the Foundation's Health Equity Fellowship Program was conceived as a means of training early-career urologists who are passionate about humanitarian work within the US so that they can be effective in engaging with diverse communities, especially those most marginalized, and become leaders within urology. The 2-year fellowship consists of 1 year of certificate-granting didactic programming in partnership with the Center for Urban Bioethics at the Lewis Katz School of Medicine at Temple University. At the end of year 1, the fellow will submit a capstone project which will be supported in year 2 by a grant and ongoing mentoring.

In July, Dr Randy Vince was selected as our inaugural health equity fellow. Dr Vince is known for his passion for helping others, specifically when it comes to disparities in urologic care for prostate cancer. He is the director of Minority Men's Health at the Cutler Center for Men at University Hospitals and an assistant professor of urology at Case Western Reserve University. We are excited to support Dr Vince's dedication to humanitarianism and his commitment to helping the field of medicine to "do better" when it comes to health equity.

UCF has a storied history of supporting young researchers, many of whom have become leaders in urology. We are now supporting and developing the urological humanitarian leaders of the future as well. We continue to evolve to improve urological care globally. Please visit urologyhealth.org/humanitarianism to learn more about the UCF's humanitarian initiatives, apply for funding, and support our efforts. ■

Table 1. The Urology Care Foundation™ Humanitarian Recognition Award Winners

Award recipient	Institution/practice
Catherine Rhu deVries, MD, FACS	Evanston, Wyoming
Sakti Das, MD	Lafayette, California
Serigne Magueye Gueye, MD	Dakar, Senegal

Table 2. The Urology Care Foundation™ Humanitarian Grant Program Awardees

Grant recipient	Institution/practice	Project location
Victoria Y. Bird, MD	University of Florida	Gainesville, Florida
Stephanie J. Kielb, MD	Northwestern University Feinberg	Rwanda
Una Jeanie Lee, MD	Virginia Mason Urology	Uganda
Ian S. Metzler, MD	Oregon Health & Science University	Trinidad and Tobago
David E. Rapp, MD	University of Virginia	Belize
Lee Richter, MD	Georgetown University	Rwanda
Samit Sunny Roy, MD, MSPH	University of Tennessee	India
Timothy G. Schuster, MD	The Toledo Hospital dba ProMedica Toledo Hospital	Belize
Kymora Scotland, MD	University of California Los Angeles	Los Angeles, California
Rajiv Singal, MD, FRCSC	Michael Garron Hospital	Malawi
Amar Singh, MD	University of Tennessee College of Medicine Chattanooga	India
Suzette Sutherland, MD	University of Washington	Senegal
Dana Weiss, MD	The Children's Hospital of Philadelphia	India
Alan J. Yaghoubian, MD	Icahn School of Medicine at Mount Sinai	India
Kit Yuen, MD	University of Rochester	Rochester, New York

Is his

PSA DOUBLING TOO FAST?

At the time of BCR in nmCSPC, PSA doubling time (PSADT) has been shown to be one of the most reliable indicators of the risk for further progression.[1,2]

Following definitive therapy, a rapid **PSADT ≤9-12 months indicates an increased risk** of prostate cancer-related morbidity and mortality.[1-3]

American Urological Association (AUA) Guidelines and NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) offer direction for understanding BCR following radical prostatectomy and radiation therapy.[4,5]

Learn more. Visit **PSADoubling.com**

AUA = American Urological Association; BCR = biochemical recurrence; NCCN = National Comprehensive Cancer Network; nmCSPC = non-metastatic castration-sensitive prostate cancer; PSA = prostate-specific antigen.

References: 1. Albertsen PC, Hanley JA, Penson DF, Fine J. Validation of increasing prostate specific antigen as a predictor of prostate cancer death after treatment of localized prostate cancer with surgery or radiation. J Urol 2004(6 Pt 1):2221-5. **2.** Ward JF, Blute ML, Slezak J, et al. The long-term clinical impact of biochemical recurrence of prostate cancer 5 or more years after radical prostatectomy. J Urol 2003;170(5):1872-6. **3.** Freedland SJ, Humphreys EB, Mangold LA, et al. Risk of prostate cancer-specific mortality following biochemical recurrence after radical prostatectomy. JAMA 2005;294(4):433-9. **4.** Lowrance W, Dreicer R, Jarrard DF, et al. Updates to advanced prostate cancer: AUA/SUO guideline (2023). J Urol 2023;209(6):1082-1090. **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.1.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed April 22, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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