FDA Document Suggests Higher Number of Duodenoscope Incidents Than Previously Reported

On January 13, 2016, Democratic Members of the Senate Committee on Health, Education, Pensions, and Labor (HELP) issued a staff report titled "Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients" on the issue of bacterial transmissions by duodenoscopes.

This report found: "Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide."[1]

The House Committee on Oversight and Government Reform obtained a new document from the Food and Drug Administration (FDA) that indicates that the problem could be significantly greater than previously reported.[2]

This document covers the time period from January 1, 2010, to October 31, 2015, and includes incidents in which duodenoscopes were contaminated, as well as patients that were infected or exposed to bacteria. According to this document, there have been:

- as many as 404 patient infections;
- 44 additional patient exposures to contaminated devices;
- 41 facilities experienced incidents in the U.S. and abroad—30 in the United States and 11 overseas;
- 34 incidents in which patients were infected or exposed to contaminated devices; and
- 319 Medical Device Reports (MDR) on patient infections, exposure, and device contamination.

The document suggests that even these numbers could be underestimated: "In some cases, the MDR mentioned 'at least XX patients' in which case there could be additional patients involved." The document also states: "In 17 reports MDRs [sic], there was mention that the scopes had device contamination after use—which indicates that it was used on at least one patient, even though the patient was not mentioned in the report."

FDA states that these "reports likely contain duplicate patient reporting," and "estimate[s] the number of unique patients reported to be 300 to 350 patients." FDA further clarifies that the "number of patients reflects only numbers mentioned in the MDR reports." This continues to

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[1] Democratic Staff, Senate Committee on Health, Education, Labor, and Pensions, *Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients* (Jan. 2016) (online at www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf).

[2] Food and Drug Administration, *Table: MDR Counts and Patient Counts by User Facility* (Feb. 15, 2016).

raise concerns that the FDA is unaware of the true number of patients affected nationally and is limited to only those reported.

In addition, many infections have been attributed to patients rather than duodenoscope procedures when their infections were caused by common bacteria. According to the American Society of Microbiology:

> Until recently, most infections have been attributed to the patient's own bacterial flora penetrating the normal barriers into the blood stream. For example, a blood stream infection caused by *Escherichia coli* (a normal part of the human bowel flora) would be attributed to that patient's own *E. coli* and no further investigations would be performed. As such, we may be underestimating the incidence of transmission events.[3]

The Senate report agreed, finding:

> [B]ecause the hospitals that have reported infections are primarily large, well-resourced research hospitals adept at spotting and addressing antibiotic-resistant infections, it is likely that there have been more incidents of infections linked to these devices that were never identified.[4]

The Senate report also warned:

> However, conversations between Senator Murray's HELP Committee staff and hospital staff, state and local health departments, and manufacturers have revealed a disconcerting lack of awareness that these reporting obligations even exist.[5]

[3] Letter from Susan E. Sharp, President-Elect, American Society for Microbiology, to House Oversight and Government Reform Committee Staff (Oct. 14, 2015).

[4] Democratic Staff, Senate Committee on Health, Education, Labor, and Pensions, *Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients* (Jan. 2016) (online at www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf).

[5] *Id*.

Food and Drug Administration
Table: MDR Counts and Patient Counts By User Facility (Feb. 15, 2016).

TABLE: MDR COUNTS AND PATIENT COUNTS BY USER FACILITY

USER FACILITY NAMED IN MDR REPORTS (1/1/2010-10/31/2015)	MDRs mentioning Patient Infections	MDRs mentioning Patient Exposure	MDRs mentioning Device Contamination	TOTAL MDRS	Patients Infected	Patients Exposed	Total Patients
Facility 1	2	8	0	**10**	2	8	**10**
Facility 2	10	1	2	**13**	57	1	**58**
Facility 3	1	0	0	**1**	1		**1**
Facility 4	1	0	0	**1**	1		**1**
Facility 5 (international)	0	0	2	**2**			**0**
Facility 6	6	0	0	**6**	6		**6**
Facility 7	6	0	0	**6**	8		**8**
Facility 8	0	4	0	**4**	0	4	**4**
Facility 9 (international)	5	0	0	**5**	5		**5**
Facility 10 (international)	4	0	0	**4**	7		**7**
Facility 11	3	0	0	**3**	3		**3**
Facility 12	22	0	0	**22**	23		**23**
Facility 13 (international)	4	0	1	**5**	4		**4**
Facility 14	0	0	1	**1**			**0**
Facility 15	6	0	0	**6**	7		**7**
Facility 16	0	0	1	**1**			**0**
Facility 17	0	2	0	**2**		2	**2**
Facility 18	16	0	0	**16**	16		**16**
Facility 19 (international)	0	0	2	**2**			**0**
Facility 20 (international)	32	0	0	**32**	32		**32**
Facility 21	6	0	0	**6**	6		**6**
Facility 22	0	0	1	**1**			**0**
Facility 23	4	0	0	**4**	4		**4**
Facility 24	0	0	1	**1**			**0**
Facility 25	2	0	0	**2**	2		**2**
Facility 26 (international)	1	0	0	**1**	1		**1**
Facility 27	0	2	0	**2**		4	**4**
Facility 28	8	0	3	**11**	8		**8**
Facility 29	0	0	1	**1**			**0**
Facility 30	16	0	1	**17**	22	9	**31**
Facility 31	4	0	0	**4**	8		**8**
Facility 32	7	0	0	**7**	7		**7**
Facility 33	7	0	0	**7**	8		**8**
Facility 34	20	0	0	**20**	40		**40**
Facility 35	1	0	0	**1**	1		**1**
Facility 36 (international)	12	0	0	**12**	12		**12**
Facility 37 (international)	4	0	0	**4**	4		**4**
Facility 38	0	2	0	**2**		2	**2**
Facility 39	2	12	1	**15**	2	13	**15**
Facility 40	39	0	0	**39**	79		**79**
Facility not specified	19	1	0	**20**	28	1	**29**
Grand Total	**270**	**32**	**17**	**319**	**404**	**44**	**448**

* - NOTE: Number of patients reflects only numbers mentioned in the MDR reports. In some cases, the MDR mentioned "at least XX patients" in which case there could be additional patients involved. These reports likely contain duplicate patient reporting (ie, same affected patient, more than once).
We estimate the number of unique patients reported to be 300 to 350.

NOTE: There were a total of 448 patients mentioned in the 319 reports. In 17 reports MDRs, there was mention that the scopes had device contamination after use -- which indicates that it was used on at least one patient, even though the patient was not mentioned in the report. Therefore 448 + 17 = 465 patients.
The highlighted institutions are foreign hospitals - 88 patients were identified here. There were 6 additional ones that were outside of US, but the hospital was not specifically identified. Therefore, 88 + 6 = 94 patients OUS.