도서발간등록번호(G000DY2-2018-123)

내시경실 환자 안전 관리 방안 및 평가기준 개발

최종보고서

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I. 연구개발결과 요약문

연구과제명	내시경실 환자 안전 관리 방안 및 평가기준 개발		
중심단어	내시경실, 합병증, 안전 지표		
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서론: 우리나라에서 내시경검사는 가장 빈번하게 시행되는 검사 중 하나이며 시술 건수도 매우 빠른 속도로 증가하고 있다. 그러므로 증가하는 내시경 건수와 더불어 내시경 관련 합병증 및 내시경실에서 발생할 수 있는 안전사고에 대해서도 관심을 기울여야 한다. 내시경을 시행받는 환자의 안전을 위해 포괄적이고도 구체적인 안전 관리 지표를 개발하고 수가 책정 등을 통해 의료기관이 이러한 지침을 따르도록 유도하는 것이 필요하다.

방법: 2017년도 국내에서 시행된 내시경 자료를 건강보험심사평가원의 청구자료로 분석하였다. 조작적 정의를 통해 종별 내시경 건수와 합병증의 빈도를 조사하였다. 내시경실의 정의를 비롯해 내시경실의 환자 안전 관리 관련하여 국내 외 문헌고찰을 하였다. 이를 통해 세계적인 환자 안전 관리 기준을 파악하였다. 문헌고찰을 바탕으로 서구에서 권고하는 지침에 맞게 항목을 구성하였고, 항목에 맞게 국내 내시경실의 실태와 현황을 알아보기 위해 설문조사를 기획하였다. 국내를 대표하는 50개 종합병원과 상급종합병원을 대상으로 하였다. 설문조사를 통해 안전 관리 지표를 선정하였다.

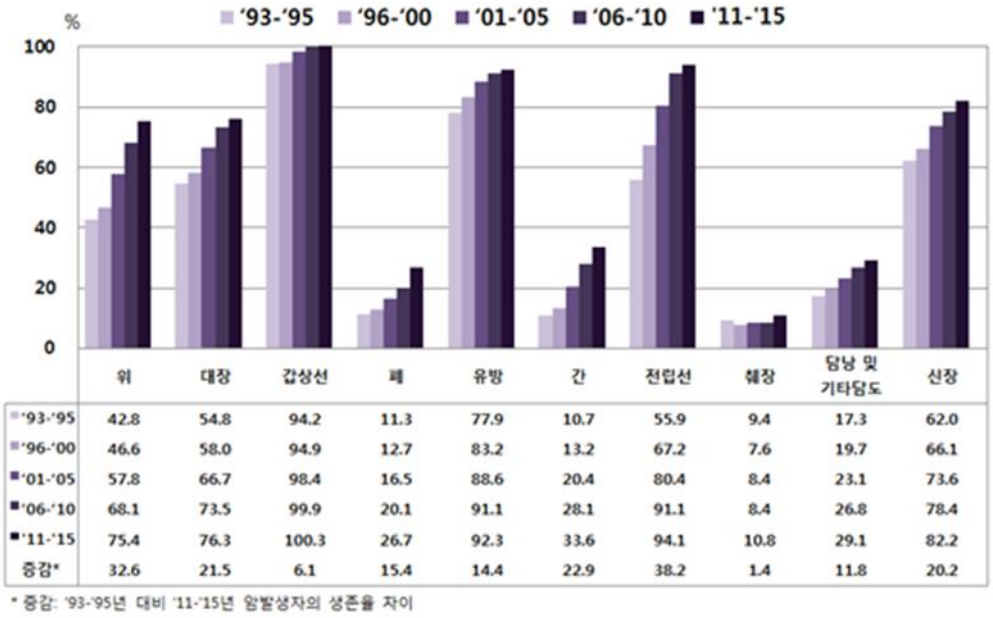
결과: 내시경실 구성, 내시경 안전 관련 규정 및 지침 보유, 검사실 필요 장비, 회복실 필요 장비, 세척실 환경, 적절한 검사실 수, 검사실 당 적절한 근무 인력, 근무 인력 중 유지 및 보수 교육을 정기적으로 받는 인력 비율, 내시경 전 환자 평가, 진정내시경 전 환자 평가, 개인보호 장비, 회복실 퇴실 기준, 내시경검사 후 환자 관리, 감염 관리, 내시경 시설 및 환경 관리 교육, 안전사고의 보고 및 개선 비율, 내시경 합병증 발생률, 내시경 합병증 발생 시 대처, 내시경세부전문의 비율, 회복실의 적절한 간호인력, 검사실당 회복실 침상 비율, 진정내시경 동안 환자 감시 비율 등의 22개 지표를 선정하였다.

결론: 내시경검사와 내시경실 환경은 감염, 출혈, 천공 등의 합병증을 유발할 수 있다. 안전과 관련된 여러 지침과 규정을 준수하고 안전한 내시경을 위한 내시경실 환경을 구축해야 한다. 지표를 바탕으로 각 기관마다 시행한 검사 수 대비 필요한 검사실, 의료인력의 수를 예측한다면 적절한 병원 평가에 도움이 되고 현실적인 수가 산정에 도움이 될 것으로 보인다.

II. 연구 배경

우리나라에서 내시경검사는 가장 빈번하게 시행되는 검사 중 하나이며 시술 건수도 매우 빠른 속도로 증가하고 있다. 그러므로 증가하는 내시경 건수와 더불어 내시경 관련 합병증 및 내시경실에서 발생할 수 있는 안전사고에 대해서도 관심을 기울여야 한다. 건강검진을 제외한 2017년도 상부소화기내시경은 약 344만 건, 대장내시경은 약 211만 건이 요양급여비용으로 청구되었다. 국민건강보험공단 건강검진 통계연보에 따르면, 위내시경은 2013년에 4,729,407건에서 2016년 6,048,812건으로 27.9% 증가하였고, 결장경은 2013년도 103,547건에서 2016년도 117,143건으로 13.1% 증가하였다.[1] 이러한 배경에는 1999년부터 수립된 '암 정복 10개년 계획'에 기인한 바가 크다. 2004년 전 국민 5대 암(위, 간, 대장, 유방, 자궁경부암) 검진 서비스 체계가 구축되었다. 2006년도에는 '제2기 암정복 10개년 계획'이 시작되었다. 제1기 사업 평가 후 국가 암조기검진사업의 암 발견율 저조와 암검진기관의 질을 평가하기 위한 제도 미비가 지적되었다. 이를 위하여 양질의 암검진 보장 강화 차원으로 암종별 표준 검진 매뉴얼 개발·보급과 양질의 검진을 보장하기 위해 인력·장비·결과 등에 대한 정기적 평가를 위한 암검진기관 질 평가제도를 도입·실시키로 하였다. 2008년 암조기검진사업에 참여하는 의료기관들이 양질의 검진에 대한 인식을 같이 하고 나아가 검진의 질 향상을 도모할 필요성에 따라 2008년 2월 검진 암종별로 질 지침을 개발·보급하였다. 이로써 국가적으로 암검진사업의 양적 성장의 토대가 마련되었고, 공공건강검진의 급속한 양적 성장이 이루어졌다. 또한, 국민의 암 검진에 대한 조기 발견, 완치 인식이 높아짐에 따라 수검률이 지속적으로 상승하였고 관련 국가 재정 지원 확대가 되었다.[2] 2011-2015년 발생한 암 환자의 5년 상대생존율(이하 생존율)은 70.7%로 최초 암 진단 이후 10명 중 7명 정도가 5년 이상 생존하는 것으로 분석되었다. '암 정복 10개년 계획' 시행 이전인 1993-1995년과 비교할 경우 대부분 암의 5년 생존율이 증가했으며, 특히 전립선암(38.2%p), 위암(32.6%p), 간암(22.9%p), 대장암(21.5%p)의 5년 생

존율이 많이 향상되었다.



	위	대장	갑상선	폐	유방	간	전립선	췌장	담낭 및 기타담도	신장
'93-'95	42.8	54.8	94.2	11.3	77.9	10.7	55.9	9.4	17.3	62.0
'96-'00	46.6	58.0	94.9	12.7	83.2	13.2	67.2	7.6	19.7	66.1
'01-'05	57.8	66.7	98.4	16.5	88.6	20.4	80.4	8.4	23.1	73.6
'06-'10	68.1	73.5	99.9	20.1	91.1	28.1	91.1	8.4	26.8	78.4
'11-'15	75.4	76.3	100.3	26.7	92.3	33.6	94.1	10.8	29.1	82.2
증감*	32.6	21.5	6.1	15.4	14.4	22.9	38.2	1.4	11.8	20.2

* 증감: '93-'95년 대비 '11-'15년 암발생자의 생존율 차이

그림 1. 주요 암종 5년 상대생존율 추이: 남녀 전체 (단위: %)

2001-2005년의 53.8% 대비 16.9% 증가하였고, 주요 암 조기 발견 시 90% 이상 생존하는 것으로 분석되었으며, 2011-2015년 암 발생 중 국가 암검진사업 대상인 위암, 대장암, 간암, 자궁경부암의 2011-2015년 발생자에 대한 5년 생존율은 각각 75.4%, 76.3%, 33.6%, 79.9%로, 미국(2007-2013년)의 31.1%, 66.3%, 18.5%, 68.8%에 비해 10%p 이상 높았다.[3-5]

표 1. 5 년 암 생존율 국제 비교 (단위: %)

암종	한국 ('96-'00)	한국 ('01-'05)	한국 ('11-'15)	미국 ('07-'13)	캐나다 ('06-'08)	일본 ('06-'08)
모든 암	44.0	54.0	70.7	69.2	60	62.1
위	46.6	57.8	75.4	31.1	25	64.6
대장	58.0	66.7	76.3	66.3	64	71.1
갑상선	94.9	98.4	100.3	98.2	98	93.7
폐	12.7	16.5	26.7	19.5	17	31.9
유방	83.2	88.6	92.3	91.1	87	91.1
간	13.2	20.4	33.6	18.5	19	32.6
전립선	67.2	80.4	94.1	99.2	95	97.5
췌장	7.6	8.4	10.8	8.7	8	7.7
자궁경부	80.0	81.4	79.9	68.8	73	73.4

그러나 국가 암검진사업의 확장으로 내시경의 시행 건수는 증가하였으나, 국가 암검진사업에서 관찰되는 암 발견율은 일반적으로 소비자가 직접 찾는 암전문기관의 암 발견율에 비해 현저하게 낮아, 국가에서 제공하는 암 검진 서비스 질에 대한 국민의 불만과 분쟁이 증가하게 되었다. 이에, 국가에서 암검진사업

의 질 평가를 시행하게 되었다.

2008년부터 보건복지부의 위탁으로 시작되어 2017년까지 이루어진 대한소화기내시경연구재단의 국가 암 검진사업의 내시경 질 평가는 암 검진을 시행하는 기관에 대해서만 정부기관이 주도하는 질관리 사업이다. 2009-2010년까지 평가에서는 암검진기관을 대상으로 질 평가 및 평가의 필요성 확산과 동기부여, 암 검진 현황 파악 및 향후 목표 설정에 필요한 기초자료 확보가 목표였다면, 2011년 과도기적 모델을 거치면서, 2012년과 2014년에 걸쳐서는 국가 건강검진기관 평가와 통합모델 구축 완료, 평가도구의 안정화, 평가 결과의 실질적 활용이라는 목표로 하였다.

2012-2014년에 걸쳐서 이루어진 1주기 평가사업은 평가항목이 변경되었고, 현장평가를 전담할 수 있는 평가단의 구성이 필요하였기 때문에 평가위원 양성 교육을 시행하였다. 또한 평가위원에 따라 기준의 적용이 달라지는 것을 최소화하기 위하여 논란이 될만한 부분은 논의를 통해 기준을 최대한 구체적으로 하였고, 수차례 위원 교육을 통해 2013년에는 2012년 기준 병원급 암검진기관 1,016기관(위: 828, 대장: 643), 2014년에는 2013년 기준 의원급 검진기관 3,000여 기관(위: 2,023, 대장: 1,289)을 대상으로 수정 보완된 평가기준에 따라 이루어졌다.

내시경검사의 질을 현장평가가 아닌 서면평가로 시행하는 데는 많은 제한이 있지만, 1주기 평가 대상인 4,000여 기관에 대해 모두 현장평가를 시행하는 것은 현실적으로 매우 어렵기 때문에, 일차적으로 서면평가를 후 일부 기관을 선별하여 현장평가를 진행하였다. 서면평가의 많은 제한점에도 불구하고, 소화기내시경 분야에서 주요 질관리 지표를 평가를 통해 계몽할 수 있을 뿐만 아니라 수검기관의 자체 질 향상 노력에도 도움이 될 수도 있으며, 서면평가를 통해 현장평가 대상 기관을 선정하여 효율적인 평가를 도모할 수도 있었다.

통합 2주기 평가는 2015-2016년에는 병원급 검진기관을 대상으로, 2016-2017년에는 의원급 검진기관을 대상으로 시행하였고, 1주기와 비교하여 이전 평가에서 얻은 결과를 토대로 소독 분야를 중심으로 한 근거 항목의 재조정이 이루어졌다. 2016년에는 제3차 암관리종합계획(2016-2020)이 수립되어 국립암센터를 중심으로 암 연구사업과 체계적인 국가 암관리사업이 진행되고 있으며, 근거중심의 국가 암 검진 프로그램 고도화와 국가 암 검진 질관리 강화를 명시하고 있다. 이를 위해, 검진 암종별로 '질 지침'을 개발·보급함으로써 국가 암검진사업에 참여하는 의료기관들이 양질의 검진에 대한 인식을 같이 하고 검진의 질 향상을 도모하고자 하였다. 2008년에 발간된 초판 이후 10년 만에 전면개정된 질 지침이 발표되었고, 이를 반영하여, 2018년부터 시행 중인 통합 3주기 평가는 기존과 비교하여 대폭 개정이 이루어져 진행될 예정이다.

질 평가사업과 더불어, 국가 암 검진 내시경 질 평가 결과가 미흡한 기관을 대상으로 멘토링 사업을 시행하며, 지속적이고 표준화된 멘토링 사업을 위한 전문위원 양성 교육을 시행하고 있다. 멘토링 사업은 질 평가를 통해 미흡한 평가를 받은 기관에 대해서 교육을 통해서 질 향상을 유도하고자, 2011년 국가 암 검진 내시경 질 평가에서 기준 점수 미달로 사후 관리 대상으로 지정된 기관 중 6개의 위내시경 기관과 1개의 대장내시경 기관들에 대하여 2012년 멘토 스쿨이 진행되었다. 멘토 스쿨의 교육 효과를 평가하기 위하여 참여 기관을 대상으로 하여, 서면평가를 다시 진행하여 긍정적인 결과를 얻었다. 그러나 부적합 판정을 받은 의료기관이 표준화되고 양질의 질 향상을 얻기 위해서는 단체 교육이 아닌 방문 멘토링 교육이 효과적일 것으로 판단되어, 통합 1주기 검진기관평가에서 미흡한 평가를 받은 기관을 대상으로 2015년과 2016년에 걸쳐서 이루어졌다. 2017년과 2018년에는 통합 2주기 검진기관평가에서 미흡한 기관을 대상으로 멘토링 교육을 진행하여, 암 검진 내시경검사의 전반적인 질 향상을 기대한다.

국가 암 검진에 대한 질 평가와 멘토링 사업의 시행으로 각 병원마다 적절한 설비와 환경, 인력을 갖추게 되었다. 질병을 정확히 진단하는 정도관리는 개선되었지만 수반하여 내시경 관련 안전사고에 대한 관심도 증가하였다.

최근 신문, 방송 등 대중매체에서 부적절한 관리에 대한 보도 후에 내시경 소독이 큰 이슈가 된 바 있다. 내시경검사는 고가의 복잡한 구조의 장비를 여러 사람을 대상으로 하여 반복적으로 사용해야 하기 때문에 감염성 질환의 전파가 가능하며 이에 대한 철저한 예방과 대비책이 필요하다. 내시경실과 내시경 및 관련 장비에 의한 감염의 빈도는 매우 낮은 것으로 알려져 있지만,[6] 최근 미국을 비롯한 여러 나라에서 소화기내시경과 연관된 감염사고가 다수 보고되었다.[7,8] 미국 네바다주의 병원에서 한 주사기를 여러 사람에게 나누어 사용하여 다수의 C형간염이 발생하였고,[7] 플로리다주와 테네시주의 재향군인병원에서 관류튜브(irrigation tube)를 교환하지 않고 다수의 환자에게 내시경을 시행하면서 감염환자가 발생하였다.[8] 현재까지 국내에서는 이러한 감염 발생의 보고가 없지만, 최근 메르스 사태와 C형간염 전파 등으로 국민의 감염에 대한 관심이 어느 때보다 높은 실정이다. 그리고 심심치 않게 언론을 통해 보도되는 내시경 관련 사망사고는 국민으로 하여금 내시경검사에 대한 두려움을 갖게 하여 그 유용성이 입증된 내시경 검진은 물론 꼭 내시경검사가 필요한 사람들에게도 검사에 대한 거부감을 불러오고 있다. 따라서 소화기내시경을 시행 받는 환자의 안전을 위해 내시경실의 환자 안전 관리에 대한 지표를 마련하고 이를 평가하여 정착시킨다면 환자의 안전을 더욱 향상시킬 수 있을 것이다.

국내에서는 아직 대한소화기내시경학회에서 발표한 내시경 세척 및 소독에 관한 지침만 있을 뿐 그 외 환자 안전 관리에 대한 지침은 없는 상태이다. 다만, 국가 암검진기관 평가항목과 대한소화기내시경학회에서 주관하는 우수내시경실 인증제 평가항목에 환자 안전 관리의 일부가 포함되어 있을 뿐이다. 2014년

발간된 미국의 소화기내시경학회(American Society of Gastrointestinal Endoscopy) 안전 가이드라인은 최근까지 내시경 소독과 감염관리에 집중되어 있으며, 한국의 내시경실 현실과는 약간의 차이가 있을 수 있다.[9] 따라서, 내시경을 시행 받는 환자의 안전을 위해 포괄적이고도 구체적인 안전 관리 지표를 개발하고 수가 책정 등을 통해 의료기관이 이러한 지침을 따르도록 유도하는 것이 필요하다. 이를 통해 국가 차원의 환자 안전 관리로 국민이 더욱 안전하게 내시경을 시행 받는 환경을 조성할 수 있을 것이다.

Ⅲ. 연구 목적 및 목표

본 연구는 우리나라 내시경실의 현황을 조사하고 분석함으로써 안전 관련 의료의 질 문제를 진단하고 향후 제도적 개선방향을 제시하고자 한다.

1. 연구 목적

본 연구에서는 1) 국내 내시경 시행 건수 및 합병증 빈도를 조사하고, 2) 종합병원과 상급종합병원의 내시경실 현황을 조사하고, 3) 외국의 사례들을 참고하고, 4) 관련 전문가의 의견을 수렴하여 이를 근거로 우리나라 내시경실 환자 안전 관리 향상의 현실적이며 구체적인 방안을 제시하고자 한다.

2. 연구 목표

1) 종합병원과 상급종합병원의 내시경실 현황을 고려하여 내시경실 안전 관리 지표를 제시한다. 지표의 적용 범주는 우선 종합병원과 상급종합병원을 대상으로 한다.

2) 이를 기준으로 의원급과 병원급 기관의 안전 관리 지표를 확대 제시한다.

Ⅳ. 연구 내용 및 방법(그림 2)

1. 2017년 국내 내시경 현황 분석

내시경실의 안전 관리 지표를 설정을 위해 2017년 국내에서 시행된 내시경의 현황을 분석하였다. 건강보험심사평가원으로부터 2017년 1월 1일부터 12월 31일까지 1년 동안 청구자료를 받아 1) 1년간 종별로 내시경(상부위장관내시경, 결장경, S상결장경, 내시경적 역행성 담췌관조영술) 청구 건수, 2) 종별, 외래, 입원 환자별, 내시경 종류별로 내시경 시행 후 발생한 합병증(출혈, 천공)의 빈도를 조사하였다. 상부위장관, 하부위장관, 췌담도 전문 연구위원들에 의해 각 내시경별 합병증의 조작적 정의를 설정하였다. 내시경검사 코드와 조작적 정의를 통해 두 명의 통계 전문가가 내시경 건수와 합병증 빈도를 조사하였고 통계 처리하였다.

1) 내시경검사 코드

(1) E7611: 상부소화관내시경검사(esophagogastroduodenoscopy, EGD)

(2) E7621: 내시경적 역행성 담췌관조영술(endoscopic retrograde cholangiopancreatography, ERCP)

(3) E7660: 결장경검사(colonoscopy)

(4) E7680: S상결장경검사(sigmoidoscopy)

2) 소화기 내시경하 시술(치료내시경)

(1) Q7620: 내시경적 상부 소화관 출혈 지혈법

(2) Q7680: 결장경하 출혈 지혈법

(3) Q7630: S상결장경하 출혈 지혈법

(4) Q7652: 상부 점막절제술 및 점막하종양절제술(endoscopic mucosal resection, EMR)

(5) QZ933: 상부 점막하 박리 절제술(endoscopic submucosal dissection, ESD)

(6) Q7701: 결장경하 폴립절제술(polypectomy)

(7) Q7703: 결장경하 점막절제술 및 점막하종양절제술

(8) QX706: 결장경하 점막하 박리 절제술

(9) Q7751: S상결장경하 폴립절제술

(10) Q7752: S상결장경하 점막절제술 및 점막하 종양절제술

2. 문헌분석

내시경실의 정의를 비롯해 내시경실의 환자 안전 관리와 관련하여 국내외 문헌고찰을 하였다. 이를 통해 세계적인 환자 안전 관리 기준을 파악하였다. 또한 기존에 제안된 안전 관리 지표를 나열하였고, 이 중에서 국내 의료 환경에서 적용 가능한 지표들을 조사하여 분석하였다. 더불어 의료기관인증 조사지침서(의료기관 평가인증원)를 참조하여 내시경실에 적용 가능한 안전 평가지침을 분석하였다. 안전 관리 지표와 이와 관련된 연구 결과들을 조사하여 연구의 설계방법, 연구의 질, 결과의 일관성 등을 분석하여 타당성을 평가하고 근거의 질을 평가하였다. 또한 근거 수준과 타당성이 높은 지표와 전문가 집단이 권고하는

지표들을 선별하여 국내 적용 가능한 후보 안전 관리 지표를 선정하기로 기획하였다.

2018년 6월 1일부터 7월 15일까지 기존 지침 검색을 위하여 국내외의 전자데이터베이스 및 진료지침 검색 자료원 등을 포함한 다양한 검색 자료원을 이용하였다. Medline, Medline Systematic Review, Medline Clinical Study, Ovid Medline, EMBASE, Web of Science 및 Cochrane Library의 전자데이터베이스를 이용하였고, 국내 검색엔진으로는 KoreaMed, 한국의학논문데이터베이스, 국회도서관, 한국교육학술정보원을 이용하였으며, 이외 Google Scholar, Scopus 및 진료지침 검색 자료원인 미국의 National Guideline Clearinghouse, 국제진료지침협의체인 GIN의 International Guideline Library, 캐나다의 CMA Infobase를 검색하였다. 검색 색인단어는 "endoscopy", "gastrointestinal endoscopy", "Endoscopy unit", "Safety", "guideline"으로 내시경 관련 안전, 안전사고와 진료지침 관련 색인단어의 조합으로 검색하였다. 진료지침 선정기준은 다음과 같다. 1) 근거 중심의 진료지침일 것, 2) 국어 혹은 영어로 쓰여진 진료지침, 3) 2000년부터 2017년 12월 사이에 발표된 진료지침일 것, 4) 개정판이 있는 경우 최신판 기준, 5) 외부 검토가 이루어진 전문가 합의 진료지침을 포함할 것 등이다. 일차 문헌 선정은 체계적 문헌고찰의 경험이 있는 문헌정보학 전공자인 의학도서관 사서가 위에 언급한 방법에 의해 검색을 실시하여 Endnote (Endnote X3®, Thomson Reuters, New York, USA)와 Excel (Excel 2010®, Microsoft, Redmond, Washington, USA)에 각각 정리하여 검색어 간에 교차검색을 통해 중복 문헌을 제외시켰다. 문헌의 제목과 초록을 보고 선택기준과 제외기준을 모두 만족하는 문헌을 선별한 후, 지침 선택을 위하여 두 명의 심사자가 독립적으로 문헌의 전문을 확인하여 본 연구에 적합한지 여부를 판단하여 일치하는 경우 선택하였고, 불일치하는 경우 두 심사자 간에 의견을 조율하였으며, 의견 조율이 되지 않는 경우 연구책임자와 상의하여 결정하였다. 문헌검색을 통해 4개의 진료지침이 선정되었다.[9-12] (첨부자료 1-4)

3. 실태조사

문헌조사를 바탕으로 서구에서 권고하는 지침에 맞게 항목을 구성하였고, 항목에 맞게 국내 내시경실의 실태와 현황을 알아보기 위해 설문조사를 실시하였다. 의료기관 단위(상급종합병원, 종합병원, 병원, 의원급) 중에 병원급과 의원급은 수가 많고 현실적으로 설문조사를 시행하기 어려워, 우선 자료 수집이 용이한 상급종합병원과 종합병원을 대상으로 하였다. 대한소화기내시경학회의 내시경질관리위원회 소속 상급종합병원과 종합병원 13곳을 대상으로 설문조사를 하였다.

설문조사에는 다음의 사항을 포함하였다(부록 1. 설문자료).

1) 근무하는 의료인력의 현황

2) 검사실 및 회복실의 침대 수, 세척실의 수와 규모를 포함한 전체 내시경실의 규모

3) 환자의 활력증후(혈압, 산소포화도, 심전도)를 검사할 수 있는 장비의 현황 및 산소 공급 장치의 유무와 수

4) 2013년부터 2017년까지 시행되었던 전체 진단 및 치료 상부소화관내시경, 결장경 시행 건수

5) 동일기간에 발생하였던 내시경 관련 출혈, 천공, 사망 등의 위중한 합병증, 진정 관련(호흡저하, 혈압저하, 아나필락시스, 쇼크 등), 환자 관리 관련(낙상 등), 소독 관련(감염 등) 합병증의 발생 건수 및 빈도, 각 항목에 대한 경과(사망, 수술, 입원치료, 심폐소생술, 기관 삽관, 제세동 시행 유무)

6) 내시경 전에 환자 상태를 파악할 수 있는 사전점검표 및 동의서 유무

7) 국가 암검진기관 평가지침 및 대한소화기내시경학회 우수내시경실 인증제 평가지침 중 환자 안전 관련 평가항목 및 기준 조사

8) 국가 암검진기관 및 우수내시경실 인증제 평가 결과를 통해 국내 내시경시행 의료기관의 안전 지침 준수 현황 파악

그 외에 기관별로 마련되어 사용되는 환자 안전 관리 지침서를 수집하였다. 수집 시 의료기관명은 삭제하고 의료기관 단위(종합병원, 상급종합병원 등)만 기재하였으며 연구 외에 자료 유출을 막기 위해 연구자에 대한 교육 및 서약서를 취득하였다.

안전사고 발생현황은 기관의 민감한 정보이므로 자료 수집 시 의료기관명을 삭제하였고 의료기관 단위만을 기재하였으며 파일에 비밀번호를 부여하여 취급하며 연구 종료 후 폐기하였다.

13개 기관의 설문조사 분석 후에 일부 항목을 수정 보완한 후 전국 50개 상급종합병원 및 종합병원으로 확대하여 같은 설문조사를 시행하였다(부록 2. 추가 설문자료).

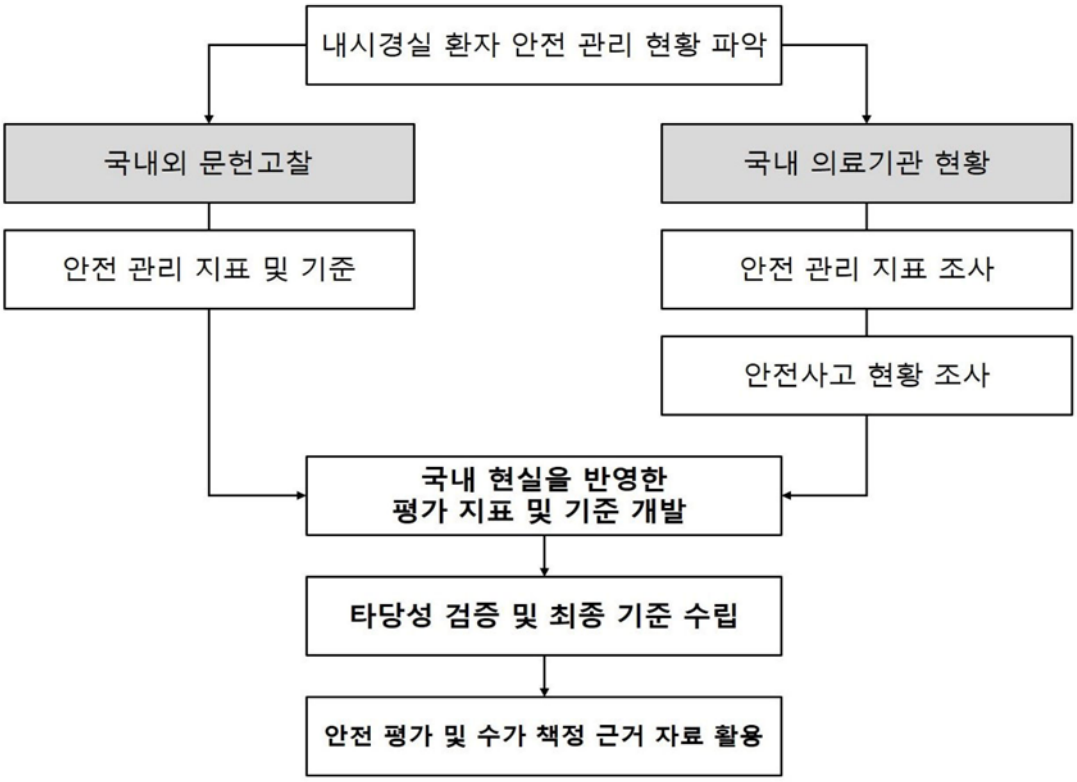


그림 2. 연구 흐름도

V. 연구 결과

1. 2017년 청구자료로 알아본 내시경 현황

1) 내시경 시행 건수

표 2. 종별 내시경 시행 건수

2017 년 종별 내시경 시행 건수							
의료기관	상부소화관내시경		결장경		S 상결장경		ERCP
	진단	치료	진단	치료	진단	치료	
의원	1,064,738	5,104	635,164	398,581	32,052	536	0
병원	276,591	1,840	253,392	135,395	13,054	366	8
종합병원	628,347	15,179	344,106	163,243	42,284	1,458	1,021
상급종합병원	444,968	20,440	175,928	65,145	33,598	1,518	2,355
합계	2,414,644	42,563	1,408,590	762,364	120,988	3,878	3,384

ERCP, endoscopic retrograde cholangiopancreatography (내시경적 역행성 담췌관조영술).

중복 청구와 건강검진 내시경을 제외하고 상부소화관내시경은 2,457,207건, 결장경은 2,170,954건, S상결장경은 124,866건, 내시경적 역행성 담췌관조영술은 3,384건이 시행되었다. 진단 상부소화관내시경은 의원에서 가장 많이 시행되었고(44.1%), 치료 상부소화관내시경(점막절제술, 점막하 박리 절제술)은 상급종합병원(48.0%)에서 가장 많이 시행되었다. 진단 결장경은 역시 의원에서 가장 많이 시행되었고(45.1%), 치료 결장경(폴립절제술, 점막절제술, 점막하 박리 절제술)은 의원(52.3%)에서 가장 많이 시행되었고 상급종합병원에서는 8.5%만 시행되었다.

표 3. 2017년 연령별 내시경 건수

2017 년 연령별 내시경시행 건수							
연령	상부소화관내시경		결장경		S 상결장경		ERCP
	진단	치료	진단	치료	진단	치료	
<20	35,241	56	7,977	404	2,830	10	8
20-29	210,642	586	50,897	6,340	9,420	74	62
30-39	421,498	1,790	143,979	42,520	11,240	303	153
40-49	309,269	3,765	275,429	120,120	15,102	662	284
50-59	508,122	9,782	429,003	240,814	21,599	1,069	587
60-69	481,340	13,734	331,425	224,888	21,234	869	781
70-79	343,702	10,599	147,844	111,315	22,386	582	930
>80	104,830	2,251	22,036	15,963	17,177	309	579
합계	2,414,644	42,563	1,408,590	762,364	120,988	3,878	3,384

ERCP, endoscopic retrograde cholangiopancreatography (내시경적 역행성 담췌관조영술).

연령별로 세분화하였을 때 진단 상부소화관내시경은 50대에서, 치료 상부소화관내시경은 60대에서 가장 많이 시행되었다. 진단 및 치료 결장경은 50대에서 가장 많이 시행되었다.

표 4. 2017년 진료 유형별 내시경 건수

2017 년 진료 유형별 내시경시행 건수							
의료형태	상부소화관내시경		결장경		S 상결장경		ERCP
	진단	치료	진단	치료	진단	치료	
외래	2,077,760	8,283	1,278,621	647,949	63,372	2,497	362
입원	336,884	34,280	129,969	114,415	57,616	1,381	3,022
합계	2,414,644	42,563	1,408,590	762,364	120,988	3,878	3,384

ERCP, endoscopic retrograde cholangiopancreatography (내시경적 역행성 담췌관조영술).

진단 상부소화관내시경은 외래에서 주로 시행되었으며(86.0%), 치료내시경은 진단되면 입원해서 시행하였다(80.5%). 진단 결장경은 일반적으로 외래에서 시행되었고(90.8%), 치료내시경 또한 외래에서 비교적 많이 시행되었다(85.0%).

2) 내시경 합병증 빈도

표 5. 2017년 종별 내시경 합병증 빈도

2017 년 종별 내시경 합병증 발생률												
의료기관	상부위장관내시경						결장경					
	진단			치료			진단			치료		
	내시경 건수	천공*	출혈*	내시경 건수	천공*	출혈*	내시경 건수	천공*	출혈*	내시경 건수	천공*	출혈*
의원	1,064,738	0.034	0.172	5,104	0.588	4.898	635,164	0.000	1.294	398,581	0.038	2.579
병원	276,591	0.051	0.662	1,840	6.522	22.283	253,392	0.036	0.884	135,395	0.074	4.010
종합병원	628,347	0.331	3.983	15,179	8.696	41.636	344,106	0.087	2.624	163,243	0.239	4.080
상급종합병원	444,968	0.649	5.715	20,440	5.577	31.556	175,928	0.296	4.746	65,145	0.553	7.307
합계	2,414,644	0.227	2.241	42,563	6.132	31.553	1,408,590	0.065	1.976	762,364	0.131	3.559

* 1,000건 당 비율

2017년도에 종별로 시행된 내시경의 합병증 빈도를 조사하였다. 내시경 관련 합병증은 내시경검사와 직접적인 연관성이 비교적 명확한 출혈 및 천공의 발생을 조사하였고 폐렴 등 감염 및 심정지 등을 비롯한 기타 합병증은 그 관련성을 청구자료로 확인하기 어려워 조사에서 제외하였다. 대부분의 내시경 관련 합병증은 출혈 후 7일 이내 확인되지만 발생일과 청구일의 차이가 있는 청구자료의 특성상 검사 후 30일 이내 합병증 발생을 조사하였다. 출혈은 내시경 시행 후 30일 이내 출혈 관련 상병(위식도열상출혈증후군, 상세불명의 위창자 출혈, 목구멍 출혈 등)으로 내원하였거나 내시경적 지혈술, 혈관색전술, 혹은 수술(혈관결찰술 등)의 청구 코드가 있는 경우로 정의하였다. 천공의 경우 천공 관련 상병(상부위장관내시경[식도의 천공, 종격동의 고름집, 창자의 천공, 상세 불명의 복부 내 기관의 손상, 달리 분류되지 않은 처치 중의 우발적 천자 또는 열상 등], 결장경[급성 복막염, 직장 및 결장의 손상, 상세 불명의 복부 내 기관의 손상, 달리 분류되지 않은 처치 중의 우발적 천자 또는 열상 등])으로 내원하였거나 천공 치료의 청구 코드(일차 봉합술, 장 절제술 등)가 있는 경우로 정의하였다. 의원, 병원, 종합병원, 상급종합병원에서 발생한 진단 상부소화관내시경의 천공, 출혈의 빈도는 각각 0.0034%/0.0172%, 0.0051%/0.0662%, 0.0331%/0.3983%, 0.0649%/0.5715%였다. 천공, 출혈 모두 병원 규모가 커질수록 증가하는 경향이 있었다. 의원, 병원, 종합병원, 상급종합병원에서 발생한 치료 상부소화관내시경의 천공, 출혈의 빈도는 각각 0.0588%/0.4898%, 0.6522%/2.2283%, 0.8696%/4.1636%, 0.5577%/3.1556%였다. 천공, 출혈 모두 종합병원에서 가장 많이 발생하였다.

의원, 병원, 종합병원, 상급종합병원에서 발생한 진단 결장경의 천공, 출혈의 빈도는 각각 0.000%/0.1294%, 0.0036%/0.0884%, 0.0087%/0.2624%, 0.0296%/0.4786%였다. 천공, 출혈 모두 상급종합병원에 가장 많이 보고되었다. 의원, 병원, 종합병원, 상급종합병원에서 발생한 치료 결장경의 천공, 출혈의 빈도는 각각,

0.0038%/ 0.2579%, 0.0074%/0.4010%, 0.0239%/0.4080%, 0.0553%/0.7307%였다. 치료 상부소화관내시경과는 달리 치료 결장경검사에서는 상급종합병원에서 천공, 출혈의 발생 빈도가 제일 높았다.

표 6. 진료 유형별 내시경 합병증 빈도

2017 년 진료 유형별 내시경 합병증 발생률												
의료형태	상부위장관내시경						결장경					
	진단			치료			진단			치료		
	내시경 건수	천공*	출혈*	내시경 건수	천공*	출혈*	내시경 건수	천공*	출혈*	내시경 건수	천공*	출혈*
외래	2,077,760	0.033	0.275	8,283	0.483	2.294	1,278,621	0.018	1.074	647,949	0.022	1.463
입원	336,884	1.419	14.367	34,280	7.497	38.623	129,969	0.523	10.856	114,415	0.752	15.426
합계	2,414,644	0.227	2.241	42,563	6.132	31.553	1,408,590	0.065	1.976	762,364	0.131	3.559

* 1,000건 당 비율

진료 유형별 내시경 합병증의 빈도도 분석하였다. 외래와 입원 시 시행한 진단 상부소화관내시경의천공, 출혈의 빈도는 각각 0.0033%/0.0275%, 0.1410%/2.4367%였다. 치료내시경은 각각 0.0483%/0.2294%, 0.7497%/ 3.8623%였다. 외래와 입원 시 시행한 진단 결장경의 천공, 출혈의 빈도는 각각 0.0018%/0.1074%, 0.0523%/ 1.0856%였다. 치료 결장경은 각각 0.0022%/0.1463%, 0.0752%/1.5426%였다.

2. 문헌 검색

선정된 진료지침을 분석하여 내시경실의 안전사고에 대한 지표를 공간 및 설비, 감염방지, 의료인력, 진정내시경으로 나누어 정리하였다.

1) 공간 및 설비

내시경실은 내시경과 관련 치료가 이루어지는 공간으로 검사실, 세척실, 회복실, 접수 및 대기공간, 투약실, 상담실, 의료인 대기공간, 교육 및 회의실로 구성되며, 의사, 간호사, 간호조무사, 의료보조인

력이 근무하는 공간이다.[13] 내시경실은 환자의 혈액, 분비물, 세척제, 소독제와 같은 유해 물질에 노출될 수 있는 오염구역과 청결구역이 공존하는 공간이므로 내시경 및 관련 부속기구 및 의료인의 동선이 제한적이다. 검사를 받는 환자의 동선은 접수, 투약실, 대기공간, 검사실, 회복실로 이루어지며, 내시경 스코프(scope)는 보관장에서 검사실, 검사 후에 세척실로 세척 및 소독, 건조 후에 보관장으로 이동한다. 이 때 세척실에서 오염공간과 청결공간은 구분되어야 하며, 오염된 스코프와 소독 후에 청결한 스코프의 이동 동선이 겹치면 안된다.

⑴ 검사실 면적: 추천되는 절대적인 면적의 기준은 없으나 진단내시경 검사실과 치료내시경실을 포함하여 4-6 m^2

⑵ 환자 및 의료진, 내시경 및 부속기구의 이동이 청결구역과 오염구역으로 나누어 동선이 정해져 있고 이에 대한 지침의 존재

⑶ 검사실에 독립된 산소 공급, 흡입 장치, 전류 공급 장치가 있고, 제세동 장치의 구비 유무

⑷ 회복실 공간에 대한 적절한 크기는 제시된 바 없지만 진정내시경 후 환자가 회복하여 퇴실할 때까지 감시할 수 있는 장치가 있어야 하고 환자의 개인정보 노출을 방지하도록 하여야 한다.

⑸ 약제 보관

2) 감염방지

⑴ 감염방지를 위한 지침서 구비: 손 위생, 개인보호장비, 안전한 약물 투여, 오염공간의 청소 및 소독을 실시한다.

⑵ 손 위생: 손 위생은 감염원의 전파 방지에 매우 중요한 과정으로 환자와의 접촉 전, 후, 오염원 노출 후, 시술 후, 주사 후, 장갑을 벗고 난 이후에도 시행한다. 감염환자나 오염원에 직접 접촉 후에는 알콜이

함유된 로션보다는 물과 비누로 손 위생을 시행한다.

⑶ 개인보호장비의 착용에 대한 지침이 구비되어야 한다. 오염원에 노출되는 정도에 따라 개인보호장비는 차등적으로 착용한다. 오염원이나 유독물질에 직접 노출될 수 있는 곳에서는 장갑, 방수 가운, 마스크, 보호 안경을 착용하여야 하며, 이 공간을 벗어날 때에는 개인보호장비를 벗고 퇴실해야 한다. 개인보호장비는 재사용해서는 안된다.

⑷ 안전한 약물 투여를 위해 주사약제는 독립된 공간에서 무균적으로 제조해야 하며, 즉시 투여하는 약제가 아닐 경우 표시라벨을 붙여 보관한다. 조제된 주사약제는 한 사람에게만 투여하고 주사기는 재사용을 금지한다.

⑸ 세척 및 소독, 유독물질에 노출되었을 경우에 대한 지침을 구비해야 한다. 검사실을 비롯하여 오염구역은 자주 청소 및 소독을 시행한다. 아침 검사 전과 오후 검사 종료 후에 시행하며 검사실이나 세척실은 오염원에 노출되었을 경우 바로 세척과 소독을 시행한다. 세척액과 소독액을 각각 사용해야 하며, 직접 노출은 없지만 손길이 자주 닿는 컴퓨터 자판, 책상, 모니터는 자주 세척을 시행한다. 재사용 기구나 장비에 대한 관리지침을 구비해야 한다.

3) 의료인력

진정내시경 동안 검사실에는 반드시 1명의 간호사가 있어야 하며, 추가 인원은 검사 진행에 도움이 되나 안전에 도움이 된다는 사실이 증명되지 않았다. 검사실 배치 인력 수는 환자의 상태(중한 질환의 유무)나 시술의 난이도에 따라 조정될 수 있다. 그러므로 내시경검사 전에 환자의 병력 청취, 신체검사를 시행한다. 완화된 진정(moderate sedation)은 의사의 감독하에 간호사가 진정약물을 투여하여 달성하며, 깊은 진정(deep sedation)은 마취과 의사와 관련 인력이 시행한다. 회복실에서 간호사는 환자의 활력징후를 체크

하고 퇴실할 때까지 가까이서 관찰한다. 환자 당 적절한 간호인력 수의 기준은 제시되지 않았다. 의료진에 대해서 진정약제 투여, 환자 활력징후의 체크, 내시경 보조, 심폐소생술에 대한 지속적인 교육이 이루어져야 하며 이에 대한 지침을 구비해야 한다.

4) 진정내시경

진정내시경의 깊이와 시간은 환자 및 시술의 난이도에 따라 결정해야 한다. 회복실에서 퇴실할 수 있는 지침이 구비되어야 하며, 진정내시경 전에 환자의 병력을 청취하고 신체검사 및 활력징후를 검사한다. 진정내시경 시행 전과 중간, 시행 후에 활력징후를 체크한다. 산소 공급 및 흡입기, 혈압계, 산소포화도 계측기, 심전도를 구비해야 한다. 진정약제는 감시를 철저히 하며 이중 잠금 장치가 설치된 보관장에 관리한다. 진정약제의 길항제를 구비해야 하며, 진정내시경과 관련된 약물, 인력, 교육, 환자 감시에 대한 지침을 구비해야 한다.

3. 설문조사를 통한 각 병원의 현황 및 실태조사

2018년 8월 1일부터 8월 30일까지 대한소화기내시경학회 산하의 내시경질관리위원회에서 작성한 설문지를 13개의 상급종합병원 및 종합병원의 소화기센터에 요청하여 설문을 시행했다. 설문은 내시경 안전사고와 관련되어 총 109문항으로 구성되었으며, 온라인 설문조사 사이트인 Survey Monkey (https://ko.surveymonkey.com/)를 이용해 연구를 진행하였다. 결과는 중간보고서에 제출하였다. 이를 바탕으로 설문 문항을 추가하여 총 132개 문항을 작성하였다. 2018년 10월 15일에서 11월 15일까지 전국 50개 종합병원 및 상급종합병원을 대상으로 확대하여 설문조사를 시행하였다.

1) 각 병원의 현황 및 실태

(1) 상급종합병원은 31곳(62%), 종합병원은 17곳(34%), 병원은 2곳(4%)이었다. 병원의 위치는 서울에 17곳(34%)으로 가장 많이 위치하고 있었으며, 경기 7곳, 대구 6곳, 부산 4곳 순이었다.

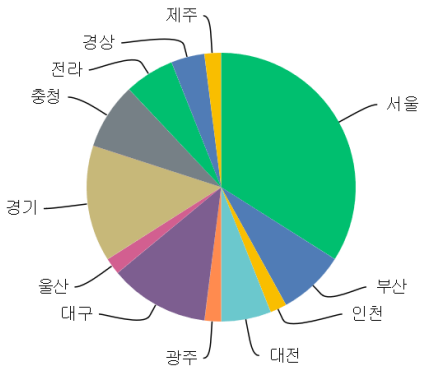
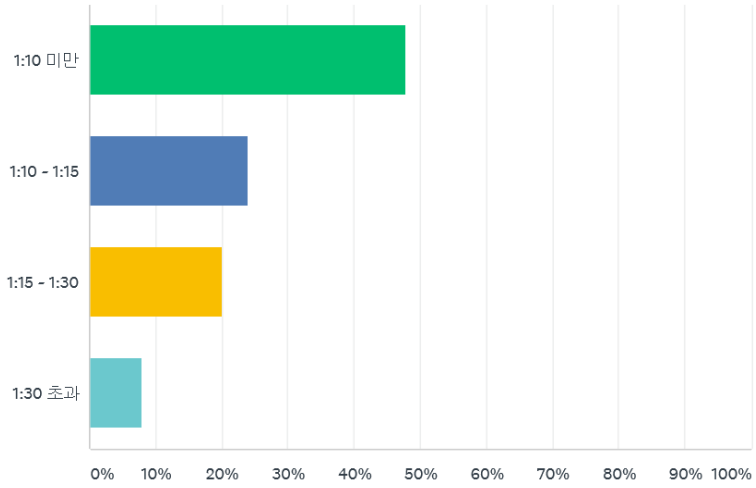


그림 3. 설문조사 병원의 위치

(2) 근무 인력

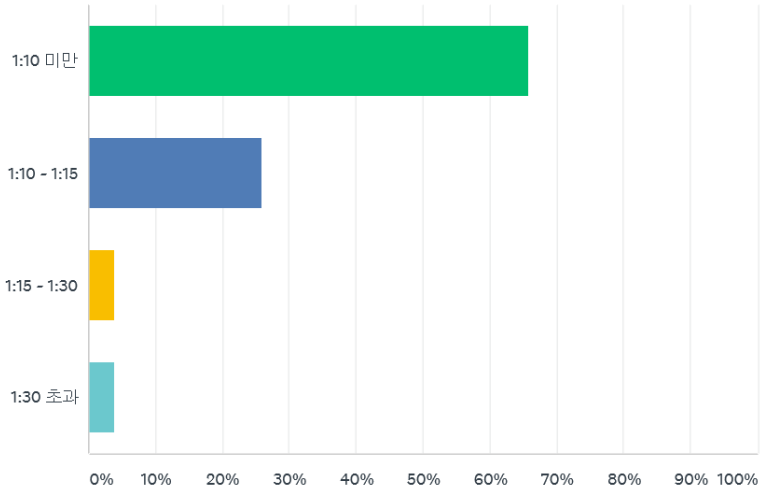
근무하고 있는 내시경의사 수는 평균 15.7±9.9명(5-58명)이었다. 이 중 대한소화기내시경학회에서 인정한 내시경세부전문의는 평균 10.2±5.2명(3-34명)이었다. 전체 간호사는 평균 14.7±10.7명(3-65명)이었고, 간호조무사는 평균 1.4±2.5명(0-17명), 세척인력과 호송요원은 평균 2.9±3.2명(0-17명)이었다. 회복실에서 근무하는 간호사는 평균 1.5±1.2명(0-6명), 간호조무사는 평균 0.04±0.2명(0-1명), 보조인력은 평균 0.14±0.5명(0-2명)이었다. 회복실 전담 간호인력/환자 비율은 그림 4와 같다. 간호사 1명이 보는 환자 수가 10명이 안 되는 병원 24개 병원(48%)이었다.



보기	응답	
1:10 미만	48.00%	24
1:10 ~ 1:15	24.00%	12
1:15 ~ 1:30	20.00%	10
1:30 초과	8.00%	4

그림 4. 회복실 전담인력: 환자 비율

회복실의 침상 수 당 환자 비율은 그림 5와 같다. 침상 1개 당 10명 미만의 환자를 보는 병원은 33개 병원(66%)이었다.



보기	응답	
1:10 미만	66.00%	33
1:10 ~ 1:15	26.00%	13
1:15 ~ 1:30	4.00%	2
1:30 초과	4.00%	2

그림 5. 회복실의 침상 수: 환자 비율

(3) 내시경실 규모 및 시설

전체 검사실은 평균 7.9±4.2개(4-26개)를 갖추었고, 이 중 치료내시경실 개수는 3.2±2.6개(0-11개)였다. 내시경실의 넓이는 평균 14.1±6.6 m^2 (3-30 m^2)였다. 회복실의 넓이는 평균 67.8±48.7 m^2 (6.5-240 m^2)였다. 회복실 침상 수는 평균 13.8±6.7개(3-35개)였다. 모든 병원이 검사실, 세척실, 회복실, 접수실, 대기공간을 가지고 있었으며, 회복실은 검사실과 분리되어 있었다. 검사실이 구분된 방이 아닌 칸막이나 커튼으로 구분되어 있는 병원 7개 병원(14%)이었다. 내시경실 내에 독립적인 화장실은 49개 병원(98%)에서 갖추고 있었다. 49개 병원(98%)에서 환자 탈의실이 성별에 따라 분리되어 운영되고 있었다. 주사약제를 준비 또는 조제하거나 보관하는 독립된 준비실은 41개 병원(82%)에서 구비하고 있었다. 내시경실 내에 직원 및 환

자를 대상으로 교육할 수 있는 독립된 공간(회의실, 교육실)이 있는 병원은 41개(82%)였다. 또한 내시경실 외부에 교육 공간이 있는 병원은 40개(80%)였다. 내시경실 내 온도와 습도를 매일 정기적으로 확인하고 기록하는 병원은 21개(42%)였다. 인력 및 시설 현황을 표 7에 정리하였다.

표 7. 조사기관의 인력 및 시설 현황

항목	평균	표준편차	최소값	최대값
전체 내시경의사 수	15.66	9.90	5.00	58.00
내시경세부전문의	10.20	5.20	3.00	34.00
내시경인증의	2.30	4.20	0.00	14.00
내시경실 전체 간호인력 (간호사/간호조무사/보조인력)	18.99	13.67	4.00	82.00
간호사	14.66	10.72	3.00	65.00
간호조무사	1.41	2.52	0.00	17.00
보조인력	2.92	3.23	0.00	17.00
회복실 전체 간호인력 (간호사/간호조무사/보조인력)	1.68	1.47	0.00	8.00
간호사	1.50	1.23	0.00	6.00
간호조무사	0.04	0.20	0.00	1.00
보조인력	0.14	0.45	0.00	2.00
시설 및 규모				
내시경 검사실 수	7.90	4.17	4.00	26.00
치료내시경 전용 검사실 수	3.24	2.56	0.00	11.00

내시경 검사실 평균 넓이 (m^2)	14.14	6.56	3.00	30.00
회복실 넓이 (m^2)	67.82	48.72	6.50	240.00
회복실 침상 수	13.76	6.76	3.00	35.00

(4) 검사실 및 회복실의 설비

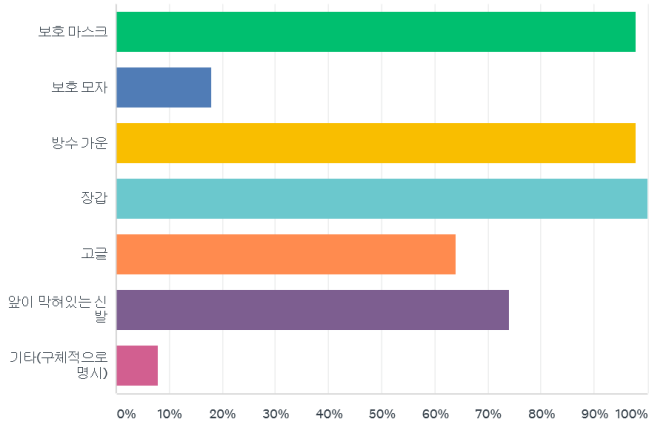
모든 병원의 검사실 내에는 산소 공급 장치와 흡입 장치가 설치되어 있었다. 검사실의 모든 침상마다 심전도/혈압/산소포화도 모니터링 시설이 구비되어 있는 병원은 44개 병원(88%)이었다. 각 검사실마다 적절한 환기 시설이 있는 병원 역시 44개 병원(88%)이었다. 검사실에 치료내시경을 대비하여 이산화탄소를 이용한 송기 시스템이 있는 병원은 37개 병원(74%)이었다.

회복실의 모든 침상마다 산소 공급이 가능하였던 병원은 43개 병원(86%)이었다. 회복실의 모든 침상마다 심전도/혈압/산소포화도 모니터링 시설을 구비하고 있는 병원은 38개 병원(76%)이었다.

내시경실 내에 유사 시 사용할 수 있는 휴대용 산소 탱크는 47개 병원(94%)에서 구비하고 있었다.

(5) 복장

내시경실 안에서 착용하는 의료인의 복장 및 개인보호장비, 탈의에 대한 규정은 46개 병원(92%)에서 갖추고 있었다. 검사실 내에서 개인보호장비를 착용하고 있는 병원은 49개 병원(98%)이었다. 검사실에서 의료진이 착용하고 있는 개인보호장비는 그림 6과 같다.



보기	응답	
보호 마스크	98.00%	49
보호 모자	18.00%	9
방수 가운	98.00%	49
장갑	100.00%	50
고글	64.00%	32
앞이 막혀있는 신발	74.00%	37

그림 6. 검사실 내 개인보호장비 구비율

(6) 각종 교육 규정

모든 병원에서 내시경실 근무 인력(의사, 간호사, 간호조무사, 보조인력)에 대한 내시경 관련 교육 규정, 소독 교육 규정, 진정 교육 규정을 구비하고 있었다. 내시경 수기에 대한 교육 규정은 45개 병원(90%)에서 구비하고 있었고, 내시경 시술 보조에 대한 교육 규정은 47개 병원(94%)에서 갖추고 있었다. 새로운 내시경 장비 및 기기에 대한 교육 프로그램은 48개 병원(96%)에서 구비하였다. 내시경 및 본체에 대한 정기검사 장부 및 수리 장부, 기록은 모든 병원에서 구비하고 있었다.

2) 환자 평가 및 합병증 기록

모든 병원에서 검사 시행 전에 성명 및 생년월일을 확인하는 등 환자 확인 절차가 있거나 시행하고있었다. 환자 상태를 사전에 파악할 수 있는 사전점검표가 있었으며, 47개의 병원(94%)에서 내시경 결과보고

서에 검사 관련 합병증을 기록하고 있었다. 26개 병원(52%)에서 결과보고서에 피검자의 주요 병력(고혈압, 당뇨병, 심장질환 등)을 기록하고 있었으며, 28개의 병원(56%)에서 결과보고서에 항혈전제 등의 약제 복용력을 기록하고 있었다. 37개의 병원(74%)에서 내시경 관련 합병증 발생 건수에 대한 통계자료를 구비하고 있었다. 모든 병원에서 내시경실의 안전사고와 관련된 치료 및 평가지침을 구비하고 있었으며 모두 질관리팀에 보고하는 시스템을 갖추고 있었다.

3) 2013-2017년 기간 동안 설문조사 병원에서의 내시경 건수

설문조사를 통해 각 병원에서 2013년부터 2017년까지 시행한 내시경 건수를 조사하였다. 진단 상부소화관내시경 건수는 2,128,207건으로 이 중 진정내시경은 62.5%인 1,329,266건이 시행되었다. 결장경은 794,804건이 시행되었으며, 이 중 진정 결장경은 598,545건(75.3%)이 시행되었다. 진정내시경은 결장경에서 상부소화관내시경보다 더 많은 빈도로 시행되었다.

표 8. 2013-2017년 50개 병원 전체 내시경 시행 건수

2013-2017년 50개 병원 전체 내시경 시행 건수							
년도		**2013**	**2014**	**2015**	**2016**	**2017**	**합계**
진단 내시경							
상부소화관 내시경	진정	248,993	262,154	253,164	278,882	286,073	1,329,266
	비진정	162,365	163,294	155,426	162,436	155,420	798,941
결장경	진정	115,341	116,994	117,012	124,741	124,457	598,545
	비진정	38,492	37,845	39,156	39,442	41,324	196,259

치료내시경							
상부소화관 내시경	ESD	9,225	10,149	5,118	5,548	5,356	35,396
	EMR	4,964	5,268	1,318	1,155	1,078	13,783
	Polypectomy	1,240	1,286	24,283	22,410	22,433	71,652
결장경	Polypectomy	27,304	25,738	24,611	28,455	31,898	138,006
	EMR	21,251	21,893	6,229	7,320	7,367	64,060
	ESD	6,716	6,853	5,118	5,548	5,356	29,591

ESD, endoscopic submucosal dissection (점막하 박리 절제술); EMR, endoscopic mucosal resection (점막절제술); Polypectomy, 폴립절제술.

상부위장관내시경 검사에서 치료내시경은 5년간 120,831건이 시행되었으며 이 중 점막하 박리 절제술은 35,396건(29.3%)이었고, 폴립절제술은 71,652건으로 전체 치료내시경 중 59.3%를 차지하였다. 치료 결장경은 총 231,657건이 시행되었고, 점막하 박리 절제술은 29,591건(12.8%)이었고 폴립절제술은 138,006건으로 59.6%를 차지하였다(표 8).

4) 2013-2017년 기간 동안 설문조사 병원에서의 내시경 후 발생한 합병증 건수 및 빈도

표 9. 2013-2017년 연도별 기관 내시경 관련 합병증 발생 건수

2013-2017년 연도별 50개 기관 내시경 관련 합병증 발생 건수									
			2013	2014	2015	2016	2017	합계	평균
출혈	위	진단	58	55	40	59	45	257	51.4
		치료	438	436	431	449	490	2,244	448.8
	대장	진단	43	42	35	34	33	187	37.4
		치료	301	327	328	346	360	1,662	332.4
천공	위	진단	8	7	8	2	5	30	6
		치료	64	89	89	75	76	393	78.6
	대장	진단	25	34	27	18	30	134	26.8
		치료	106	107	85	83	97	478	95.6
진정사고 (혈압저하/호흡저하 등)			174	162	164	178	167	845	169
낙상			13	15	15	27	24	94	18.8
사망			3	3	4	2	4	16	3.2
기타 안전사고			3	8	3	6	6	26	5.2
합계			1,236	1,285	1,229	1,279	1,337	6,366	1273.2

표 10. 2013-2017년 연도별 50개 기관별 평균 내시경 관련 합병증 발생 건수

2013-2017년 연도별 50개 기관별 평균 내시경관련 합병증 발생 건수									
			2013	2014	2015	2016	2017	합계	평균
출혈	위	진단	1.184	1.122	0.816	1.204	1.204	5.53	1.106
		치료	8.939	8.898	8.796	9.163	9.163	44.959	8.9918
	대장	진단	0.878	0.857	0.714	0.694	0.694	3.837	0.7674
		치료	6.143	6.673	6.694	7.061	7.061	33.632	6.7264
천공	위	진단	0.163	0.143	0.163	0.041	0.041	0.551	0.1102
		치료	1.306	1.816	1.816	1.531	1.531	8	1.6
	대장	진단	0.510	0.694	0.551	0.367	0.367	2.489	0.4978
		치료	2.163	2.184	1.735	1.694	1.694	9.47	1.894
진정사고 (혈압저하/호흡저하 등)			3.551	3.306	3.347	3.633	3.633	17.47	3.494
낙상			0.265	0.306	0.306	0.551	0.551	1.979	0.3958
사망			0.061	0.061	0.082	0.041	0.041	0.286	0.0572
기타 안전사고			0.061	0.163	0.061	0.122	0.122	0.529	0.1058
합계			25.224	26.223	25.081	26.102	26.102	128.732	25.7464

표 11. 2013-2017년 50개 기관별 검사 10,000건 당 내시경 관련 합병증 발생 빈도

2013-2017년 50개 기관별 검사 10,000건 당 내시경 관련 합병증 발생 빈도						
			평균	표준편차	최소값	최대값
출혈	위	진단	1.31	3.82	0.00	22.33
		치료	228.74	559.87	0.00	3500.00
	대장	진단	2.17	6.57	0.00	39.06
		치료	45.14	60.44	0.00	287.22
천공	위	진단	0.08	0.17	0.00	0.93
		치료	32.02	52.13	0.00	203.98
	대장	진단	1.39	1.78	0.00	6.94
		치료	12.60	18.53	0.00	100.13
기타			2.30	8.41	0.00	57.10

2013-2017년까지 50개 병원에서 시행되었던 내시경 약 300만 건을 분석한 결과를 표 9-11까지 정리하였다. 상부 진단 내시경에서 출혈은 10,000건 당 평균 1.31건(0.013%) 발생하였고, 천공은 평균 0.08건(0.0008%)이었다. 폴립절제술, 내시경 점막절제술, 점막하 박리 절제술을 포함한 상부 치료내시경에서 출혈은 10,000건 당 평균 228.74건(2.29%), 천공은 평균 32.02건(0.32%)이 발생하였다. 진단 결장경에서 출혈은 10,000건 당 평균 2.17건(0.022%), 천공은 평균 1.39건(0.014%) 발생하였다. 치료 결장경에서 출혈은 10,000건 당 평균 45.14건(0.451%), 천공은 12.60건(0.126%)이 발생하였다.

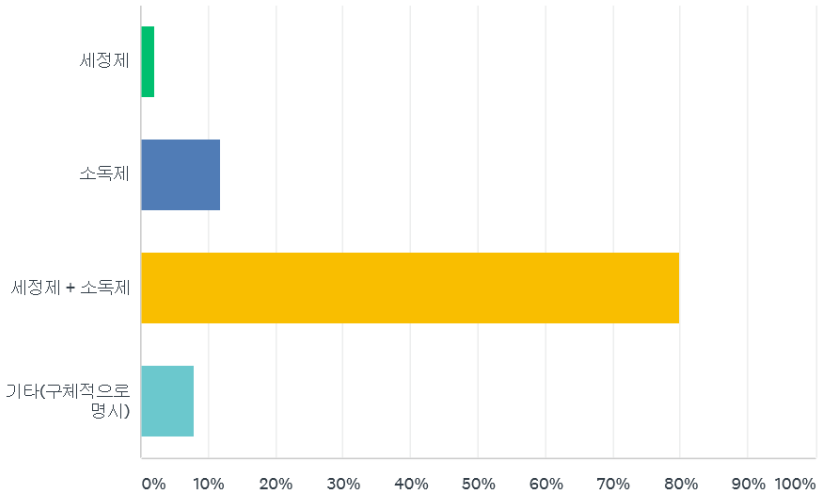
5) 성과지표

내시경 결과보고서에 위내시경 시술 시간을 기록하는 병원은 21개(42%)였다. 결장경검사 시 회수 시간을 기록하는 병원은 30개 병원(60%)이었다. 결장경검사에서 맹장삽관율은 40개 병원(80%)에서 기록하고 있었으며, 폴립발견율과 선종발견율은 12개 병원(24%)에서 주기적으로 측정하고 있었다.

6) 감염 및 소독

(1) 감염

올바른 손 씻기에 대한 규정도 모든 병원에서 구비하고 있었다. 주사약제의 보관 및 관리 투여, 폐기(1회용 주사기 등 정맥투여, 라벨)에 대한 관리 규정을 모든 병원에서 갖추고 있었다. 1회용 기구와 재사용 기구에 대한 관리 규정은 49개 병원(98%)에서 구비하고 있었다. 검사실을 포함한 내시경실 환경에 대한 청결 및 소독에 대한 지침은 모든 병원에서 구비하고 있었다. 내시경 검사 중에 사용하는 윤활젤리, 거즈 및 내시경을 통해 환자에 투여되는 물, 색소, 가스 및 거품제거제의 조제 및 보관, 폐기 등 사용 및 관리에 대한 규정은 41개 병원(82%)에서 구비하고 있었다. 내시경검사 전에 검사실과 세척실을 청소하는 병원은 45개(90%)였다. 모든 병원에서 일과 종료 후에 검사실과 세척실을 청소하고 있었다. 청소 및 소독에 사용하는 약물을 그림 7과 같다.

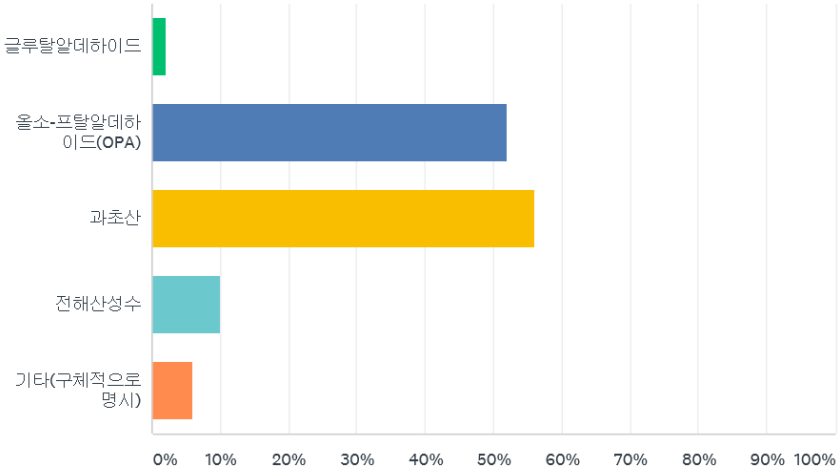


보기		응답	
세정제		2.00%	1
소독제		12.00%	6
세정제 + 소독제		80.00%	40
기타(구체적으로 명시)	응답	8.00%	4

그림 7. 내시경실에서 사용하는 청소 및 소독 약물

(2) 소독

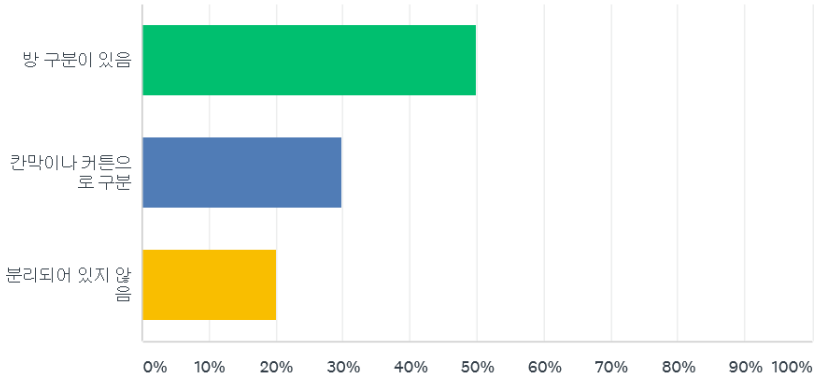
모든 병원에서 소독 및 세척에 대한 지침을 구비하였으며 지침에 맞게 시행하고 있었다. 모든 병원에서 전세척제로는 효소세정제를 사용하였고, 소독제는 보건복지부에서 고시한 고수준 소독제를 사용하고 있었다(그림 8).



보기		응답	
글루탈알데하이드		2.00%	1
올소-프탈알데하이드(OPA)		52.00%	26
과초산		56.00%	28
전해산성수		10.00%	5
기타(구체적으로 명시)	응답	6.00%	3

그림 8. 고수준 소독제

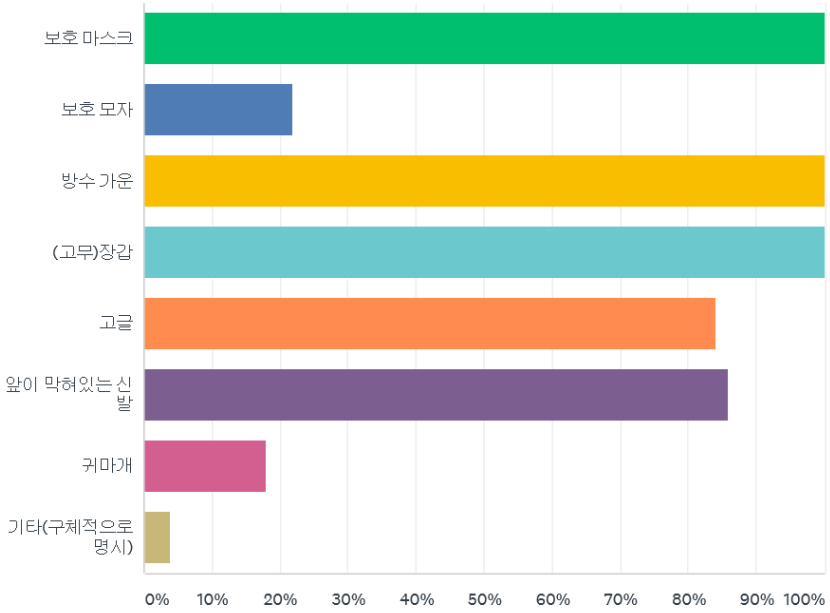
모두 세척실은 검사실과 분리되어 있었으며, 49개 병원(98%)에서 세척실 내에 적절한 환기시설을 갖추고 있었다. 환기시설로는 환기후드(75.5%), 환기창(59.2%) 등이 있었다. 검사 후에 오염된 내시경은 46개 병원(92%)에서 전용바구니에 담아 세척실로 이동하였다. 세척실 내에 오염구역과 청결구역으로 나누어진 병원은 40개(80%)였으며, 분리되지 않은 병원은 10개(20%)였다(그림 9).



보기	응답	
방 구분이 있음	50.00%	25
칸막이나 커튼으로 구분	30.00%	15
분리되어 있지 않음	20.00%	10

그림 9. 세척실 환경

검사실과 세척실 간의 내시경 이동이 세척 전에는 오염통로, 세척 후에는 청결통로로, 별도로 구분된 통로를 이용하는 병원은 35개(70%)였다. 자동소독기는 49개 병원(98%)에서 구비하였다. 소독 후 헹굼 과정에는 40개 병원(80%)에서 필터로 여과한 물 혹은 멸균된 물을 사용하고 있었다. 소독을 잘 시행하고 관리하는지 알 수 있는 지표인 균배양검사는 46개 병원(92%)에서 일정한 간격으로 시행하고 있었으며 48개 병원(96%)에서 배양지침을 구비하고 있었다. 세척실 근무자들은 모두 보호 마스크, 방수 가운, 장갑을 착용하고 있었다(그림 10).



보기		응답	
보호 마스크		100.00%	50
보호 모자		22.00%	11
방수 가운		100.00%	50
(고무)장갑		100.00%	50
고글		84.00%	42
앞이 막혀있는 신발		86.00%	43
귀마개		18.00%	9
기타(구체적으로 명시)	응답	4.00%	2

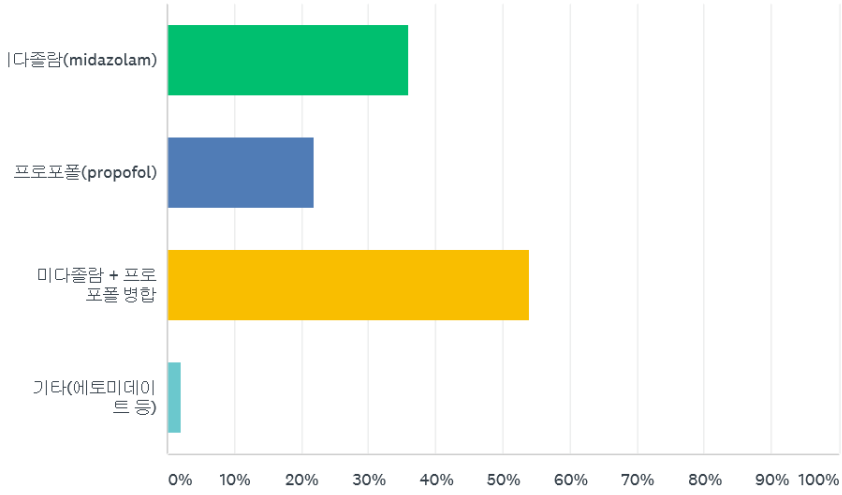
그림 10. 세척실 내에서 착용하고 있는 개인보호장비

모든 병원에서 소독실무자에 대한 교육지침을 구비하고 있었고, 관련 학회를 통한 유지 보수 교육을 정기적으로 이수하였다.

7) 진정내시경

41개의 병원(82%)에서 진정내시경검사 전 평가로 미국마취과학회에서 제시하는 환자 평가기준인 American Society of Anesthesiologist (ASA) 점수를 기록하고 있었다.[14] 사용하는 진정약제는 미다졸람

(midazolam, 36%), 프로포폴(propofol, 22%), 두 약제병합(54%), 에토미데이트(etomidate, 2%)였다(그림 11).



보기		응답	
미다졸람(midazolam)		36.00%	18
프로포폴(propofol)		22.00%	11
미다졸람 + 프로포폴 병합		54.00%	27
기타(에토미데이트 등)	응답	2.00%	1

그림 11. 진정내시경 시 사용 약제

진정약제 투여 전에 32개의 병원(64%)에서 산소 공급을 하고 있었다. 진정약제의 종류, 초기 용량, 투여 간격은 48개의 병원(96%)에서 의사가 결정하였으며, 모든 병원에서 적어도 한 명 이상의 간호인력이 보조하였다. 모든 병원에서 의료인력에 대한 진정 교육을 시행하고 있었으며, 학회에서 정기적으로 유지 보수 차원의 교육을 받고 있었다. 모든 병원에서 진정내시경 동안 산소 공급을 하고 있었고 산소포화도를 측정하였다. 진정내시경 동안 혈압측정은 37개 병원(74%)에서 이루어지고 있었으며, 심전도 모니터링은 23개 병원(46%)에서 이루어지고 있었다. 의식 수준의 평가는 44개의 병원(88%)에서 시행하였다. 모든 병

원에서 검사실에 플루마제닐(flumazenil)과 날록손(naloxone) 등의 진정약물 길항제가 구비되어 있었다. 49개 병원(98%)에서 심폐소생술을 위한 장비가 구비되어 있었고, 진정내시경 관련 합병증은 37개 병원(74%)에서 기록하고 있었다. 모든 병원에서 회복실로부터의 퇴실지침을 구비하고 있었다.

4. 내시경실 안전 관리 지표 선정

2017년 청구 결과를 분석한 내시경 건수와 합병증 발생률, 50개 병원의 내시경실 실태 조사를 바탕으로 내시경실 안전 관리 지표를 선정하였다. 적용 대상은 우선 종합병원과 상급종합병원의 내시경실로 한정하였고 이를 바탕으로 의원급과 병원급에 적용할 수 있는 지표를 세분화하였다.

내시경실 구조와 인력의 범주를 구조지표로 한정하였고, 내시경 시행과정 중에 안전과 관련된 지표를 과정지표로, 이 지표들을 바탕으로 결과지표를 선정하였다. 안전을 위해서 중요하고 바로 적용해야 할 지표를 평가지표로, 지금 당장은 아니지만 향후 질관리 개선을 통해 적용될 가능성이 있는 지표를 모니터링 지표로 구분하였다. 평가지표 18개(구조지표 8개, 과정지표 7개, 결과지표 3개)와 모니터링지표 4개(구조지표 3개, 과정지표 1개)를 선정하였다. 지표의 세부항목 중 종별로 구분하여 의원급에서도 반드시 충족해야 할 가장 기본적인 항목을 필수항목으로, 향후에 안전이나 수월한 검사를 위해 필요한 지표를 권고항목으로 구분하였다.

구 분		평가지표(안)
평가지표(18)	구조(8)	(지표 1) 내시경실 구성
		(지표 2) 내시경 안전 관련 규정 및 지침 보유
		(지표 3) 검사실 필요 장비
		(지표 4) 회복실 필요 장비
		(지표 5) 세척실 환경
		(지표 6) 적절한 검사실 수
		(지표 7) 검사실 당 적절한 근무 인력
		(지표 8) 근무 인력 중 유지 및 보수 교육을 정기적으로 받는 인력 비율
	과정(7)	(지표 9) 내시경 전 환자 평가
		(지표 10) 진정내시경 전 환자 평가
		(지표 11) 개인보호장비
		(지표 12) 회복실 퇴실 기준
		(지표 13) 내시경검사 후 환자 관리
		(지표 14) 감염 관리
		(지표 15) 내시경 시설 및 환경 관리 교육
	결과(3)	(지표 16) 안전사고의 보고 및 개선 비율
		(지표 17) 내시경 합병증 발생률
		(지표 18) 내시경 합병증 발생 시 대처
모니터링 지표(4)	구조(3)	(지표 1) 내시경세부전문의 비율
		(지표 2) 회복실의 적절한 간호인력
		(지표 3) 검사실 당 회복실 침상 비율
	과정(1)	(지표 4) 진정내시경 동안 환자 감시 비율

평가지표 1. 내시경실 구성

구분		세부내역
정의		내시경실의 외적 환경 및 근무 인력의 구성
산출식		없음
선정 근거		안전한 내시경질 환경의 지표를 산정하기 위한 기본 요소
세부기준		내시경실은 내시경과 관련 치료가 이루어지는 공간으로 검사를 시행하는 검사실, 세척실, 회복실, 상담실, 접수실 및 환자 대기공간, 청결하게 약제를 보관하고 투여하는 독립된 투약실, 의료인 대기공간, 교육 및 회의실로 구성된다.[13] 근무 인력은 의사, 간호사, 간호조무사, 의료보조인력으로 구성된다. 필수 항목: 접수실, 검사실, 세척실, 회복실, 의사, 간호사, 간호조무사 권고항목: 상담실, 독립된 환자 대기공간, 투약실, 교육 및 회의실
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 2. 내시경 안전 관련 규정 및 지침 보유

구분		세부내역
정의		안전한 내시경실 환경을 구축하기 위한 기본적인 규정 및 지침
산출식		없음
선정 근거		주관적이고 비정기적인 행위나 교육은 안전을 저해할 수 있는 환경을 제공한다. 안전한 내시경 환경과 일정한 수준의 근무 인력 환경을 평가하기 위함
세부기준		O 내시경 근무 인력(의사, 간호인력, 보조인력)에 대한 내시경 관련 교육 규정 (필수) O 내시경실 근무 인력에 대한 개인보호장비의 착용 규정(필수) O 내시경 기계에 대한 정기적인 검사 및 수리 장비 규정(필수) O 올바른 손 씻기에 대한 규정(필수) O 주사약제의 보관 및 관리, 투여, 폐기에 대한 규정(필수) O 일회용 기구와 재사용 기구에 대한 관리 규정(필수) O 공인된 내시경 소독 및 세척에 대한 지침(필수) O 정기적인 내시경 균배양검사에 대한 규정(권고)
제외기준	분자	없음
	분모	없음
비고		공인된 지침이란 저명 국제학술지에 발표된 지침으로 대한소화기내시경학회와 대한위대장내시경학회의 소독지침을 말한다

평가지표 3. 검사실 필요 장비

구분		세부내역
정의		안전한 내시경검사를 위한 검사실의 필수 장비
산출식		없음
선정 근거		안전한 검사실의 보유 장비 평가
세부기준		O 내시경 본체(필수) O 내시경 스코프(필수) O 산소 공급 장치(진정내시경 시행 기관은 필수) O 흡입 장치(필수) O 산소포화도 측정기(진정내시경 시행 기관은 필수) O 혈압계(권고) O 심전도기계(권고) O 환기 장치(권고)
제외기준	분자	없음
	분모	없음
비고		진정내시경을 시행하지 않는 기관이라도 고위험군의 환자(고혈압, 고령, 심혈관 질환, 천식)에서는 활력증후를 검사하고 산소를 공급할 수도 있으므로 가능하면 모니터링 기계를 구비할 것을 권고한다.

평가지표 4. 회복실 필요 장비(진정내시경)

구분		세부내역
정의		안전한 진정내시경을 위한 회복실 필요 장비
산출식		없음
선정 근거		안전한 회복실의 보유 장비 평가
세부기준		O 환자의 사생활 보호를 위해 침상마다 격리된 벽이나 커튼(필수) O 산소 공급 장치(필수) O 흡입 장치(필수) O 산소포화도 측정기(필수) O 혈압계(필수) O 심전도기계(권고)
제외기준	분자	없음
	분모	없음
비고		진정내시경을 시행하는 기관에 적용할 수 있는 지표로 회복실의 각 침상마다 산소 공급 장치, 흡입 장치, 산소포화도 측정기가 설치되어 있어야 하며 혈압계와 심전도기계는 침상마다 구비되어 있지 않더라도 적어도 1대는 비치되어야 한다.

평가지표 5. 세척실 환경

구분		세부내역
정의		내시경의 세척 및 소독이 이루어지는 공간의 환경
산출식		없음
선정 근거		내시경 관련 감염 예방을 위해 가장 중요한 세척실 환경 평가
세부기준		O 고수준 소독제의 사용(필수) O 세척 및 소독 장비(필수) O 자동세척기(권고) O 청결구역과 오염구역의 구분(필수) O 환기 장치(필수) O 개인보호장비(필수) O 정수 필터(필수) O 초음파세척기(권고)
제외기준	분자	없음
	분모	없음
비고		보건복지부에서 고시한 '의료기관 사용기구 및 물품 소독지침'에 기재되어 있는 고수준 소독제는 글루타르알데히드, 올토프탈데히드, 과초산 및 과산화수소, 차아염소산염(사용장소에서 전기분해로 제조된 것)이며 (참고문헌: 의료기관 사용기구 및 물품 소독지침 개정안 [보건복지부 고시 제 2017–101호]) 이들 소독제 사용 여부를 확인하고 성분을 알 수 있는 설명서가 반드시 있어야 한다. "차아염소산염은 전해살균수의 일종으로 전해살균수는 쉽게 불활성화되므로 전해살균수 제조 장치가 구비되어 소독현장에서 생성하여 바로 사용하는 것이 아니면 인정되지 않는다 (참고문헌: 소화관내시경 세척 및 소독의 길잡이 개정판)."

평가지표 6. 적절한 검사실 수

구분		세부내역
정의		기관별로 시행한 내시경 건수를 바탕으로 안전한 검사를 위한 이상적인 검사실 수 산정
산출식		○ 하루에 이루어지는 진단 상부위장관내시경 건수: - $\frac{\text{1년에 시행하는 진단 상부위장관내시경 건수}}{\text{1년에 내시경을 시행하는 일 수}}$ ○ 하루에 검사실 당 검사가 이루어지는 시간: - $\frac{\text{하루에 내시경을 시행하는 시간}}{\text{평균 시술 시간 + 준비 시간}}$ ○ 검사실 수: - $\frac{\text{하루에 이루어지는 진단 상부위장관내시경 건수}}{\text{하루에 검사실 당 검사가 이루어지는 시간} \times 0.7 \text{ (활동 변수)}}$ 예를 들어 1년에 3만 2천 건의 상부위장관내시경을 시행하는 기관에서 1년에 약 260일간 검사를 시행한다. 상부위장관내시경 검사 시간이 약 10분, 준비 시간이 10분 걸린다고 하고, 하루 6시간 동안 내시경검사를 시행한다면, 적절한 내시경 검사실의 수는 약 7개이다. 근거 자료: 참고문헌 14
선정 근거		기관에서 안전한 내시경을 시행하기 위한 적절한 검사실, 검사 수 평가
세부기준		○ 1년 동안 시행한 진단, 치료 상부위장관, 결장경검사 건수 ○ 검사 및 준비 시간의 평균 걸리는 시간
제외기준	분자	없음
	분모	없음
비고		상부위장관내시경의 진단, 치료, 결장경의 진단, 치료내시경 건수를 따로 구분하여 계산한다.

평가지표 7. 검사실 당 적절한 근무 인력

구분		세부내역
정의		검사실마다 꼭 필요한 의료인력 수
산출식		O 진단내시경(비진정, 진정), 간단한 치료내시경(폴립절제술): 검사실마다 의사 1명 이상, 간호사 1명 이상 O 복잡한 치료내시경(지혈술, 점막하 박리 절제술, 내시경적 역행성 췌담관조영술) 및 깊은 진정내시경: 검사실마다 의사 1명 이상, 간호사 2명 이상
선정 근거		천공 및 출혈과 진정내시경 관련 합병증을 최소화하거나 예방할 수 있는 의료인력의 수 평가
세부기준		O 2013-2017년 50개 기관 - 전체 내시경 건수 - 합병증 발생 건수 - 근무 인력의 수 및 변수 평가 O 단변량, 다변량 평가
제외기준	분자	없음
	분모	없음
비고		없음

1) 통계 분석 방법

상부소화관 및 결장 치료내시경 발생과 관련된 인자를 분석하기 위해 일반화 선형모델(Generalized linear models), 푸아송 회기(Poisson regression), 로그(log) 연결 함수를 이용하였다. 병원 규모, 검사 건수, 진정제 사용 종류 등의 변수들을 보정한 후 인력 및 검사실 개수에 따른 치료내시경 관련 합병증 발생의 연관성을 확인하기 위해 다변량 분석을 시행하였다. 다양한 분석 모델을 이용해 추가 분석하였고 모두 유사한 결과를 보여주었다.

2) 치료내시경 관련 합병증 관련 인자 및 영향력 분석

(1) 치료 상부소화관내시경

치료 상부소화관내시경 관련 분석에서 회복실 보조인력을 제외한 나머지 인력과 내시경 검사실 및 회복실 침상 수의 증가는 합병증 감소에 유의한 영향을 미치는 것으로 확인되었다. 내시경의사 1명이 늘어날수록 상부위장관 치료내시경 10,000건 당 합병증 건수는 0.06건씩 감소한다. 즉, 치료내시경 10,000건 당 합병증 1건을 감소시키기 위해서는 내시경의사가 대략 17명이 늘어나야 한다(1/0.06=16.67). 반면, 내시경 세부전문의의 경우 약 5명이 필요하였다(1/0.205=4.88). 간호사의 경우 내시경실 간호사가 1명 늘어날수록 상부위장관내시경 10,000건 당 합병증 건수는 0.07건씩 감소한다. 간호조무사 및 보조인력을 포함한 내시경실 전체 간호인력을 분석했을 때 내시경실 전체 간호인력 1명이 증가할 수록 합병증 건수는 0.142건씩 감소하여 상부소화관 치료내시경 10,000건 당 합병증 1건을 감소시키기 위해서는 전체 내시경 보조인력이 약 7명이 늘어나야 한다(1/0.142=7.04). 또한, 검사실 개수가 1개 늘어날수록 상부소화관 치료내시경 10,000건 당 합병증 건수는 0.64건씩 감소해 치료내시경 10,000건 당 합병증 1건이 감소하기 위해서 검사실 개수는 대략 2개씩 늘어나야 한다(1/0.64=1.56). 요약하면, 상부소화관 치료내시경 관련 합병증 발

생에 영향을 미치는 인력은 회복실 간호인력, 내시경실 전체 간호인력, 내시경의사 인력 순이었다.

표 12. 상부위장관 치료내시경 10,000건 당 합병증(출혈/천공) 관련 인자 다변량 회기 분석

	Estimate	SE	CI		*P*-value
내시경 전체 의사	-0.062	0.006	-0.074	-0.050	<0.0001
내시경세부전문의	-0.205	0.014	-0.232	-0.179	<0.0001
내시경실 간호사	-0.070	0.007	-0.083	-0.058	<0.0001
내시경실 간호조무사	-0.853	0.044	-0.939	-0.767	<0.0001
내시경실 보조인력	-0.210	0.014	-0.238	-0.182	<0.0001
내시경실 전체 간호인력*	-0.142	0.009	-0.159	-0.124	<0.0001
회복실 간호사	-0.448	0.067	-0.579	-0.316	<0.0001
회복실 간호조무사	-2.399	1.050	-4.456	-0.341	0.0223
회복실 보조인력	0.185	0.184	-0.177	0.546	0.3166
회복실 전체 간호인력*	-0.425	0.068	-0.557	-0.293	<0.0001
내시경 검사실 개수	-0.645	0.021	-0.686	-0.603	<0.0001
내시경 검사실 넓이	-0.070	0.008	-0.085	-0.055	<0.0001
회복실 넓이	-0.031	0.002	-0.034	-0.028	<0.0001
회복실 침상 수	-0.179	0.008	-0.195	-0.162	<0.0001

* 간호사, 간호조무사, 보조인력

(2) 치료 결장경

치료 결장경 관련 분석에서는 내시경의사(세부전문의 포함), 내시경실 간호사, 회복실 간호조무사, 회복실 침상 수는 합병증 발생에 유의한 영향을 미치지 않는 것으로 나타났다. 하지만 나머지 인력들(내시경실 및 회복실 전체 간호인력, 내시경실 간호조무사 및 보조인력, 회복실 간호사 및 보조인력)은 합병증 발생 감소에 유의한 영향을 미치는 것으로 확인되었다. 대표적으로, 회복실 전체 간호인력 1명이 늘어날수록 치료 결장경 10,000건 당 합병증은 0.131건 감소한다. 즉, 치료내시경 10,000건 당 합병증 1건을 감소시키기 위해서는 회복실 전체 간호인력이 약 8명 늘어나야 하는 것으로 확인되었다(1/0.131=7.63). 흥미롭게도 내시경 검사실 개수 및 넓이가 증가할수록 합병증 발생 역시 증가하는 것으로 확인되었다. 이는, 병원 규모와 검사 건수를 보정하였으나 조사 기관이 50개로 적은 한계로 규모나 내시경실 크기가 큰 기관에서 더 난이도가 높은 치료내시경 시술이 시행되었을 가능성을 생각해 볼 수 있겠다.

표 13. 치료 결장경 10,000건 당 합병증(출혈/천공) 관련 인자 다변량 회기 분석

	Estimate	SE	CI		*P*-value
내시경 전체 의사	-0.003	0.003	-0.008	0.003	0.3561
내시경세부전문의	0.005	0.005	-0.005	0.014	0.3261
내시경실 간호사	-0.001	0.002	-0.006	0.004	0.6291
내시경실 간호조무사	-0.022	0.009	-0.040	-0.003	0.0214
내시경실 보조인력	-0.068	0.008	-0.083	-0.052	<.0001

내시경실 전체 간호인력*	-0.007	0.002	-0.011	-0.003	0.0012
회복실 간호사	-0.111	0.023	-0.156	-0.065	<.0001
회복실 간호조무사	-0.136	0.131	-0.394	0.121	0.3000
회복실 보조인력	-0.465	0.061	-0.585	-0.345	<.0001
회복실 전체 간호인력*	-0.131	0.020	-0.169	-0.092	<.0001
내시경 검사실 개수	0.018	0.006	0.006	0.029	0.0021
내시경 검사실 넓이	0.013	0.003	0.007	0.019	<.0001
회복실 넓이	-0.004	0.001	-0.005	-0.002	<.0001
회복실 침상 수	0.007	0.004	0.000	0.014	0.0525

* 간호사, 간호조무사, 보조인력

평가지표 8. 내시경실 근무 인력 중 유지 및 보수 교육을 정기적으로 받는 인력 비율

구분		세부내역
정의		정기적인 내시경 관련 교육을 받는 의료인력
산출식		O $\frac{\text{정기적인 유지 보수 교육을 받는 의사 수}}{\text{전체 의사 수}} \times 100$ O $\frac{\text{정기적인 유지 보수 교육을 받는 간호사 및 간호조무사 수}}{\text{전체 간호사 및 간호조무사 수}} \times 100$
선정 근거		내시경실 근무 인력은 정기적으로 내시경 관련 교육을 받아야 한다.
세부기준		O 내시경 관련 학회의 정기적인 교육 평점 O 내시경 관련 학회에서 시행하는 정기적인 소독 및 질관리, 진정 교육 평점 O 매년 1회 이상 교육 평점을 부여 받은 근거 O 기준이 되는 평점은 1년에 6점(시간당 1점)으로 한다.
제외기준	분자	없음
	분모	없음
비고		내시경 관련 학회는 대한소화기내시경학회, 대한위대장내시경학회의 본회 및 지회의 세미나, 학술대회를 지칭한다. 기준 점수: 100%

평가지표 9. 내시경 전 환자 평가

구분		세부내역
정의		안전한 내시경검사를 위해 검사 전 환자 평가
산출식		없음
선정 근거		안전한 내시경검사를 위한 환자의 위험도 평가
세부기준		O 시술 전 평가지 또는 사전점검표(필수)에 아래 사항이 반드시 언급되어야 하며 환자에게 확인해야 한다. - 금식 여부 - 전신 상태 및 병력 - 항혈전제를 포함한 약물 복용력 - 결장경 시 장정결 상태 근거자료: 부록 3. 사전점검표(대한소화기내시경학회)
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 10. 진정내시경 전 환자 평가

구분		세부내역
정의		안전한 진정내시경검사를 위한 검사 전 및 동안 환자 평가
산출식		없음
선정 근거		안전한 내시경검사를 위한 환자의 위험도 평가
세부기준		O 시술 전 평가지 및 사전점검표(필수) O 검사 전 혈압측정(필수) O 검사 동안 의식상태, 혈압, 산소포화도, 맥박 수, 투여 약물과 용량(필수) O 환자의 이상 반응을 감시하고 기록(필수) O ASA 점수 기록지(권고) 근거자료: 부록 3. 사전점검표(대한소화기내시경학회)
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 11. 개인보호장비

구분		세부내역
정의		환자-의사 사이의 감염 방지를 위한 보호장비
산출식		없음
선정 근거		내시경실 감염 예방을 위한 안전성 평가
세부기준		O 검사실과 세척실에 근무하는 의료인의 개인보호장비 착용 및 탈착에 관한 규정 O 검사실 개인보호장비 - 마스크(필수) - 장갑(필수) - 방수 가운(필수) - 고글 및 앞이 막힌 신발(권고) O 세척실 개인보호장비 - 마스크(필수) - 장갑(필수) - 방수 가운(필수) - 방수 모자(필수) - 고글 및 앞이 막힌 신발(필수) - 귀마개(권고)
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 12. 회복실 퇴실 기준

<table>
<tr><th>구분</th><th>세부내역</th></tr>
<tr><td>정의</td><td>진정내시경검사 후에 회복실 퇴실 기준</td></tr>
<tr><td>산출식</td><td>없음</td></tr>
<tr><td>선정 근거</td><td>진정내시경검사 후에 환자의 위험도 평가</td></tr>
<tr><td>세부기준</td><td>O 회복실에서 환자의 의식 상태 평가(필수)
O 환자의 산소포화도, 혈압, 맥박 수 측정(필수)
O Aldrete Score (Adult Post procedure/Post sedation Recovery Score)[15] 9점 이상 또는 시술 전 상태와 동일하게 회복(권고)
<table>
<tr><th colspan="2">Adult Post procedure/Post sedation Recovery Score
(Aldrete Score)</th><th>점수</th></tr>
<tr><td rowspan="3">반사능력</td><td>명령 또는 자발적으로 모든 팔다리 운동 가능</td><td>2</td></tr>
<tr><td>명령 또는 자발적으로 2개의 팔다리 운동 가능</td><td>1</td></tr>
<tr><td>자발적으로 모든 팔다리 운동 불가능</td><td>0</td></tr>
<tr><td rowspan="3">호흡</td><td>심호흡 및 기침 가능</td><td>2</td></tr>
<tr><td>호흡 곤란 또는 호흡 운동 제한</td><td>1</td></tr>
<tr><td>무호흡</td><td>0</td></tr>
<tr><td rowspan="3">순환</td><td>마취-진정 전 혈압의 ±20%</td><td>2</td></tr>
<tr><td>마취-진정 전 혈압의 ±20-49%</td><td>1</td></tr>
<tr><td>마취-진정 전 혈압의 ±50%</td><td>0</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td colspan="2"></td><td>
<table>
<tr><td rowspan="3">의식상태</td><td>완전 회복 의식상태</td><td>2</td></tr>
<tr><td>부르면 눈 뜸</td><td>1</td></tr>
<tr><td>무반응</td><td>0</td></tr>
<tr><td rowspan="3">산소포화도</td><td>대기 중 산소포화도 >92% 유지</td><td>2</td></tr>
<tr><td>산소투여로 산소포화도 >90% 유지</td><td>1</td></tr>
<tr><td>산소투여에도 불구하고 산소포화도 <90%</td><td>0</td></tr>
</table>
근거자료: 부록 3. 사전점검표/진정기록지
</td></tr>
<tr><td rowspan="2">제외기준</td><td>분자</td><td>없음</td></tr>
<tr><td>분모</td><td>없음</td></tr>
<tr><td colspan="2">비고</td><td>없음</td></tr>
</table>

평가지표 13. 내시경검사 후 환자 관리

구분		세부내역
정의		내시경검사 후에 식사 및 내시경 관련 합병증의 설명
산출식		없음
선정 근거		안전한 내시경검사를 위해 검사 후 설명의 의무 평가
세부기준		O 내시경검사 후 주의사항, 합병증이 포함된 설명서 또는 동의서(필수) 근거자료: 부록 4. 위내시경 설명서 및 동의서(대한소화기내시경학회) 부록 5. 대장내시경 설명서 및 동의서(대한소화기내시경학회)
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 14. 감염관리

구분		세부내역
정의		내시경실 감염관리
산출식		없음
선정 근거		내시경 감염예방을 위해 내시경기기 및 시설에 대한 소독 및 관리지침이 있고 이에 대한 감염관리가 이루어 져야 한다
세부기준		O 내시경 기구세척, 소독, 멸균 및 세탁물 관리에 대한 감염관리 절차가 있어야 한다(필수). - 오염된 내시경 및 내시경 부속기구의 이동 방법 - 내시경 세척 및 소독: 공인된 소독지침에 따른다. - 세척직원의 개인보호장비 착용 - 세탁물 관리: 수집장소의 별도 구획, 오염 세탁물의 분리, 수집용기의 적합성, 세탁물의 운반 O 절차에 따라 사용한 기구의 세척 및 소독을 수행하여야 한다(필수). O 절차에 따라 멸균된 기구를 관리하여야 한다(필수). - 멸균방법: 재사용 기구 소독시 고압증기멸균, Ethylene Oxide gas (EO gas) 멸균 O 절차에 따라 세척직원은 보호구를 착용하여야 한다(필수). O 절차에 따라 오염된 내시경 기구 및 오염세탁물을 적절하게 관리한다(필수).
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 15. 내시경 시설 및 환경 관리 교육

구분		세부내역
정의		내시경실에 대한 환경관리가 적절하며 이에 대한 직원 교육이 이루어져야 한다
산출식		없음
선정 근거		O 내시경검사 및 시술에 필수적인 내시경기기, 부속기구, 의료시설에 대한 정기적인 검사, 유지, 보수가 시행되어야 한다. O 이에 대한 개선계획을 수립하고, 수행하여야 한다. O 내시경실 직원은 안전규정을 준수하여야 한다.
세부기준		O 내시경실 직원에 대한 안전 관리 교육이 이루어져야 한다(필수). O 내시경실 시설, 의료기기, 위험물질에 대한 안전 관리 계획 지침(권고) - 내시경실 시설물에 대한 유지, 보수, 개선활동 - 내시경실 의료기기의 종류, 예방 점검, 사용자 교육 - 위험물질의 종류, 노출 시 행동 요령 및 사용자 교육
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 16. 안전사고의 보고 및 개선 비율

구분		세부내역
정의		내시경실 안전 관리(관리지침 및 안전사고 보고)
산출식		$\frac{\text{안전사고의 보고 및 개선 건수}}{\text{안전사고 발생 건수}} \times 100$
선정 근거		O 진정내시경 및 내시경과 관련된 안전사고(감염, 낙상) 발생 시 신속히 대처해야 한다. O 안전사고 발생을 보고하여야 하며 향후 발생을 예방할 수 있는 시스템을 구축해야 한다.
세부기준		O 주사 약제의 보관 및 관리, 투여, 폐기(1회용 주사기 등 정맥 투여, 라벨)에 대한 관리 규정(필수) O 일회용 기구와 재사용 기구에 대한 관리 규정과 준수(필수) O 마약 및 진정약제 관련 지침 준수 유무(필수) O 내시경실 안전사고 발생 기록 장부(필수) O 내시경실 안전사고 발생 보고 체계(필수) O 안전사고 개선책 기록 장부(필수)
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 17. 내시경 합병증 발생률

구분		세부내역
정의		내시경 시술 관련 합병증 발생률
산출식		$\frac{\text{연간 내시경실 합병증 발생 수}}{\text{연간 전체 내시경 시행 건수}} \times 100$
선정 근거		내시경실 관련 합병증의 발생을 기록하고 보관하여야 하며, 유발인자를 분석하고, 유사 합병증의 발생을 예방하여야 한다.
세부기준		O 내시경 관련 합병증 발생 건수에 대한 월별(연도별) 통계 기록 O 기록하여야 할 내시경 관련 합병증의 종류 - 진정 관련 합병증 - 출혈 - 천공 - 기타 내시경 관련 합병증 O 내시경검사 결과보고서에는 다음 내용이 포함되어야 한다. - 검사 관련 합병증 기록 - 이상 반응 기록 - 대처 및 치료
제외기준	분자	없음
	분모	없음
비고		없음

평가지표 18. 내시경 합병증 발생 시 대처

구분		세부내역
정의		내시경 관련 합병증 발생 시 안전하게 치료할 수 있는 방법
산출식		$\frac{\text{연간 내시경 합병증 발생 대처 및 치료 건수}}{\text{연간 내시경 합병증 발생 건수}} \times 100$
선정 근거		안전한 내시경검사를 위한 평가
세부기준		O 내시경검사의 합병증(호흡저하, 쇼크, 출혈, 천공) 발생 시 대처법에 대한 규정(필수) O 출혈 및 천공을 치료할 수 있는 내시경 치료 기구(필수) O 심폐소생술 장비(필수) O 내시경 합병증 기록 장부(필수)
제외기준	분자	없음
	분모	없음
비고		기준 점수: 100%

모니터링 지표 1. 내시경세부전문의 비율

구분		세부내역
정의		안전하고 보다 전문적인 내시경 교육을 체계적으로 받은 의사
산출식		$\frac{\text{내시경세부전문의}}{\text{내시경의사}} \times 100$
선정 근거		보다 전문적이고 체계화된 내시경 교육을 받은 인력의 근무 현황 평가 설문 연구 분석 결과 내시경실에 근무하는 내시경세부전문의 수가 전체 내시경의사 수보다 합병증 발생 위험도 감소에 더 큰 영향을 미치는 것으로 나타났으며(표 13) 영국/미국 등의 서구 지침에서 능숙한 검사에 필요한 최소 대장내시경 시행 건수를 150-300건 이상으로 권고하고 있음[16-18]
세부기준		O 내시경세부전문의는 대한소화기내시경학회와 대한위대장내시경학회에서 인정하는 내시경 전문 인증의이다. O 대한소화기내시경학회 내시경세부전문의는 1년 이상의 전임의 교육을 받고, 상부소화기내시경 1,000건, 결장경 150건 이상을 시행한 경험이 있고 학회에서 주관하는 시험을 통과할 때 인정된다. 또한 3년간의 일정한 교육과 논문이 있을 경우 갱신이 된다. O 대한위대장내시경학회 내시경세부전문의는 상부소화기내시경 500건, 결장경 300건 이상을 시행한 경험이 있고, 학회에서 주관하는 시험을 통과할 때 인정된다. 근거자료:
제외기준	분자	현재 근무 중이고 내시경세부전문의 면허는 있으나 갱신이 안된 의사
	분모	없음
비고		없음

모니터링지표 2. 회복실의 적절한 간호인력

구분		세부내역
정의		안전한 환자의 회복을 위한 간호인력 수
산출식		$\frac{\text{회복실 환자 수}}{\text{회복실 간호사 수}} \leq 10$
선정 근거		회복실 근무 인력 평가 국내 의료기관 설문 연구 결과 회복실 간호인력 수가 증가할수록 치료내시경 관련 합병증 발생 빈도가 줄어드는 것으로 확인됨(표 13)
세부기준		O 회복실 환자 10명 당 1명 이상의 간호인력(권고) O 침상 당 산소 공급 가능(필수) O 침상 당 혈압, 맥박 수, 심전도, 산소포화도 모니터링 시설(필수) O 활력징후는 매 15분 간격으로 이루어져야 함(권고) O 퇴실 기준 확인(필수)
제외기준	분자	없음
	분모	없음
비고		없음

모니터링지표 3. 검사실 당 회복실 침상 비율

구분		세부내역
정의		진정내시경 시술 후 안전한 모니터링을 할 수 있는 회복실 시설이 있으며 충분한 간호인력이 있어야 한다.
산출식		회복실 침상 / 검사실 수
선정 근거		진정내시경검사에 대한 회복실 침상 확보율 평가
세부기준		O 내시경 검사실 수 O 회복실 침상 수
제외기준	분자	없음
	분모	없음
비고		기준 점수: >2 근거 자료: 참고문헌 14

모니터링지표 4. 진정내시경 동안 환자 감시 비율

구분		세부내역
정의		진정내시경 시술 전반에 걸친 환자 모니터링과 기록이 적절한지 비율
산출식		$\frac{\text{진정내시경 동안 적절한 모니터링을 시행한 건수}}{\text{전체 진정내시경 시행 건수}} \times 100$
선정 근거		진정내시경 시술 중 환자의 활력증후를 모니터링 하여야 하고 회복실로 옮긴 후에도 적절한 간격으로 환자를 감시하고 기록하여야 한다.
세부기준		O 진정 전 환자 상태를 적절하게 평가하고, 진정내시경을 시행한다(필수). O 검사 동안 활력증후를 모니터링 및 기록한다(필수). O 회복 중인 환자 상태를 모니터링하고 기록한다(필수). O 모니터링 또는 기록 내용(필수) - 산소포화도를 포함한 환자 활력증후 - 투여된 약물과 용량 - 환자의 이상 반응과 상태
제외기준	분자	없음
	분모	없음
비고		기준 점수: 100%

VI. 고찰 및 향후 연구 과제

안전한 내시경실 환경을 위해 엄격한 질관리 평가가 이루어지고 있다. 병원인증평가와 국가 암 검진 시행기관에 대한 평가, 우수내시경실 인증제가 그것이다. 병원인증평가는 2004년부터, 국가 암검진평가는 2008년부터, 대한소화기내시경연구재단에서 시행하는 우수내시경실 인증제는 2012년부터 시행되었다. 초기 질 평가의 지표는 외형적인 것에 치우쳐 있어서 인력, 시설, 동의서, 공간 및 설비에 대한 개선이 대부분이었다. 초기 외형적인 것을 구비하고 나서는 점차 검사의 질을 높이고 안전을 강화하는 지표가 추가되었다. 국내 질환경 개선에 있어서 가장 큰 문제는 인용할 수 있는 데이터와 논문이 거의 없다는 점이다. 실제로 국내에서 내시경 관련 감염사고는 보고된 적이 거의 없어, 의료진조차 내시경 관련 감염 합병증에 대해 주의를 거의 기울이지 않고 있다. 내시경 관련 출혈이나 천공 등의 합병증도 최근에서야 공식적으로 기록하는 병원들이 늘어나게 되었다. 따라서 국내보다 훨씬 소득 수준이 높고 질관리가 철저히 이루어지는 선진 사례 분석을 통해 지표를 만들게 되면서 국내 실정과는 괴리가 발생하게 되었다. 본 연구에서 많은 자료는 아니지만 2017년 건강보험심사평가원의 청구자료를 바탕으로 내시경 시행 건수를 조사할 수 있었고, 국내 50개의 상급종합병원과 종합병원의 5년간의 내시경 자료와 각 병원 내시경실의 실태를 조사하고 분석함으로써 향후 국내 안전 관리 지표 작성에 객관적인 근거를 마련한 것은 매우 고무적인 일로 생각한다.

1. 안전사고

미국 소화기내시경학회에서 제시한 안전사고는 감염, 소독, 진정내시경과 관련되어 있다.[9] 내시경 관련 감염은 주로 불완전한 소독과 1회용 기구의 재사용에 의해 발생한다.

1) 내시경과 감염

(1) 소독

내시경 소독의 목적은 내시경으로 인한 감염을 줄이는 것이다. Spaulding은 의료기구를 감염의 위험성에 따라 분류하였다.[19] 내시경은 중간 수준의 감염 위험성(semicritical, 점막에 닿지만 점막을 뚫지 않는 기구)이 있는 것으로 평가되어 높은 수준(high-level)의 소독(일부 세균성 포자를 제외한 모든 미생물을 사멸시키는 소독)을 시행할 것을 권고하였으며, 내시경 부속기구 중 인체의 조직에 생검, 절제, 관통하는 조직검사용 겸자, 주사침 등의 관혈적인 기구들은 고위험성(critical)으로 분류되어 멸균이 요구된다. 내시경검사로 인한 감염은 내인성과 외인성 감염으로 구분된다. 내인성 감염은 위장관이나 호흡기에 상주하는 균이 내시경과 관련하여 다른 부위나 혈액으로 유입되는 경우이고 외인성 감염은 오염된 내시경이나 부속물에 의해 발생하며 가장 큰 원인은 내시경의 부적절한 세척 및 소독으로 알려져 있다.[20] 한 연구에 의하면 1966년부터 1992년까지의 내시경검사에 의한 감염을 정리한 보고에서 총 281예의 감염이 있었다고 하였다.[6] 각 감염 예는 모두 올바른 소독지침을 따르지 않았거나 검증되지 않은 소독제를 사용하여서 발생한 것으로 분석되었다. 1993년 미국 소화기내시경학회의 보고에 의하면 내시경 소독지침이 제정되어 시행된 1988년부터 1992년까지 약 28예가 보고되어 내시경검사에 의한 우발적 감염은 약 180만 건의 내시경검사 당 1예의 빈도로 발생하는 것으로 추정되었다.[21] 이와 같이 검증된 소독지침에 따라 내시경을 소독할 경우, 내시경검사로 인한 감염의 빈도는 매우 낮은 것으로 추정된다. 최근 연구에 의하면 소독지침에 맞게 소독하는 기관의 순응도는 67-93%였고,[22] 검사기관의 28.4%에서는 동일한 지침에도 불구하고 소독과정이 일관되지 않았다고 보고되어, 서구화된 선진국에서도 모든 기관에서 소독지침에 맞게 재처리를 하지는 않는다는 것이 문제점으로 지적되었다.[23] 국내에서도 내시경의 올바른 소독을 위해 대한소화기내시

경학회에서는 1995년에 '내시경 기기 세척 및 소독지침'을 제정한 데 이어 2009년 8월에 개정된 '내시경 기기 세척 및 소독지침 안'을 제정하여 공포하였다.[17] 소독지침은 내시경으로 인한 감염을 줄이기 위해 근거를 중심으로 작성된 지침으로, 최소한 이 지침에 따라 소독할 것을 권고하고 있다.

본 연구에서도 모든 병원에서 소독 및 세척에 대한 지침을 구비하였으며 지침에 맞게, 전세척(precleaning), 세척(cleaning), 소독(disinfection), 헹굼(rinsing), 건조(drying)의 다섯 과정으로 시행하고 있었다. 모든 병원에서 전세척제로는 효소세정제를 사용하였고, 소독제는 보건복지부에서 고시한 고수준 소독제를 사용하고 있었다. 세척실 내에 적절한 환기시설은 갖추고 있었으나 청결구역과 오염구역을 확실하게 구분하는 시설적인 면에서는 10개의 기관이 미흡하였다. 검사실에서 끝마치고 나온 내시경은 오염구역에서 세척 및 소독이 이루어져야 하며, 소독 후에는 오염구역과 구분된 청결구역에서 건조 및 보관과정이 이루어져야 한다. 시설의 개선은 경비가 많이 소요되는 사항으로 차후 내시경실의 리모델링 시 개선될 것으로 사료된다. 또한 의원급과 병원급의 국가 암검진평가 시 제일 점수가 낮은 항목이 고수준 소독제의 사용이었다. 본 연구에서 조사한 기관에서는 모두 고수준 소독제를 사용하고 있어 문제가 없었으나 의원급과 병원급에 대한 고수준 소독제에 대한 홍보와 교육을 보다 확대해야 할 것이다.

(2) 1회용 기구 관리 및 손 씻기

미국의 내시경실에서 1회용 기구를 재사용하다 다수의 감염환자가 발생하였다.[7,8] 국내에서도 1회용 주사기의 재사용으로 인해 C형간염이 발생한 사고가 있었다. 이로 인해 1회용 기구의 재사용은 금지되었고, 1회용 기구는 한번 사용하고 난 후 반드시 폐기해야 하며, 재사용이 가능한 기구는 멸균 장치를 통해 소독할 것을 권고하고 있다. 본 연구에서도 올바른 손 씻기에 대한 규정을 모든 병원에서 구비하고 있었다. 주사약제의 보관 및 관리 투여, 폐기(1회용 주사기 등 정맥투여, 라벨)에 대한 관리 규정을 모든 병원에서

갖추고 있었다. 1회용 기구와 재사용 기구에 대한 관리 규정은 49개 병원(98%)에서 구비하고 있었다. 내시경검사 중에 사용하는 윤활젤리, 거즈 및 내시경을 통해 환자에 투여되는 물, 색소, 가스 및 거품제거제의 조제 및 보관, 폐기 등 사용 및 관리에 대한 규정은 41개 병원(82%)에서 구비하고 있었다.

2) 진정내시경

수면, 진정을 유도하는 주사제로는 벤조다이아제핀(benzodiazepines [midazolam, diazepam]), 아편제(opiates [morphine, meperidine, fentanyl]), 프로포폴이 있다. 이런 약물은 과민반응, 약물상호작용, 호흡곤란, 저혈압을 유발할 수 있다.

(1) 과민반응

과민반응은 가벼운 두드러기에서 생명을 위협하는 아나필락시스에 이르기까지 다양하게 나타날 수 있다. 내시경의사는 내시경을 시행하기 전에 환자의 과거 약물복용력, 과민반응의 유무를 철저히 파악해야 한다. 국소적으로 두드러기가 발생했을 때에는 항히스타민제를 투여하고, 아나필락시스는 경한 호흡곤란에서 저혈압, 쇼크까지 다양한 증상으로 발현될 수 있으므로 아나필락시스가 의심될 때에는 신속히 대처해야 한다. 에피네프린 1:1000 희석액 0.5 cc 근주와 항히스타민제를 정주하고, 산소포화도와 혈압, 심전도를 모니터할 수 있는 장비가 갖추어진 곳으로 환자를 옮기고 활력징후를 감시하면서, 수액, 산소를 공급하도록 한다.

(2) 약물상호작용

내시경의사는 환자가 복용하는 약물을 잘 파악하고 있어야 진정유도약물과의 상호작용으로 인해 발생할 수 있는 부작용을 사전에 예방할 수 있다. 예를 들어 azole계통의 항진균제는 벤조다이아제핀의 대사를 억제하여 혈중농도를 높이기 때문에 호흡저하와 저혈압을 더 잘 유발할 수 있으므로 주의해야 한다.

(3) 호흡곤란

Bell 등[24]은 100명의 환자에게 진정내시경을 시행하였더니 환자의 7%에서 산소포화도가 80% 이하로 떨어졌지만 중한 합병증 없이 회복하였다고 보고하였다. 벤조다이아제핀과 아편제를 함께 투여할 경우 상승작용으로 인해 더욱 더 호흡곤란을 유발할 수 있다. 그러므로 고위험군의 환자, 즉, 기저 산소포화도가 낮은 환자, 심혈관계 환자, 검사 도중 산소포화도가 떨어지는 환자에서는 진정내시경을 시행할 때 산소를 꼭 공급해야 한다. 특히 고령의 환자들은 생체변화 즉, 젊은 사람에 비해 기저 산소포화도가 낮고, 고이산화혈증과 저산소증에 대한 심혈관 반사작용이 둔감하고, 아편제에 의한 호흡곤란이 더 심하게 나타나기 때문에 꼭 산소를 공급해야 한다.[25]

(4) 저혈압

흔히 사용되는 진정유도약물인 미다졸람은 투여 허용량인 0.15-0.3 μg/kg을 주사하더라도 평균 동맥압을 10 mmHg 감소시키는 것으로 보고되고 있다. 환자가 심각한 심혈관질환이 있을 경우에 평균 동맥압을 10-20 mmHg 더 감소시킨다.[26] 더군다나 벤조다이아제핀과 아편제를 함께 투여할 경우 상승작용으로 인해 동맥압을 더 떨어뜨리는 작용을 하므로 주의를 요한다.

(5) 대처법

American Society of Gastrointestinal Endoscopy (ASGE) 지침은 진정내시경을 시행하는 모든 환자에게 혈압, 맥박, 산소포화도를 꼭 감시할 것을 권고하고 있다.[27] 젊은 환자 즉, 저위험군의 환자에게 진정내시경을 시행할 경우 산소를 꼭 투여할 필요는 없지만 기저 산소포화도가 떨어져 있을 경우와 고위험군의 환자에서는 코를 통해 약 2 L/min로 산소를 공급해야 한다. 또한 아편제와 벤조다이아제핀의 길항제 종류와 투여방법을 숙지하여 부작용이 발생하였을 때 신속히 투여할 수 있어야 한다. 플루마제닐은 벤조다이아제

핀의 길항제로 0.2 mg을 정주하고 3-5분 간격으로 반복 투여하여 총 3 mg까지 투여할 수 있다. 주의할 점은 만성적으로 벤조다이아제핀을 복용하는 환자에게 플루마제닐을 투여할 경우 발작을 유발할 수 있으므로 주의해야 한다. 날로손은 아편제의 길항제로 약 0.4 mg을 정주하고 3-5분 간격으로 반복 투여한다. 만성 아편제 복용자에게 날록손을 투여할 경우 급성 금단증상을 초래할 수 있으므로 주의해야 한다.

그러므로 반드시 진정내시경 전에 환자의 심혈관 위험도를 조사하여야 하며, 검사 기간 동안 산소를 공급해야 한다. 진정내시경 동안 또는 후에도 환자의 활력증후를 꼼꼼히 일정한 간격으로 측정하고 기록해야 한다. 심폐소생술 장비를 갖추어야 하며, 각 검사실과 회복실 침상마다 산소 공급 장치, 혈압계, 심전도, 산소포화도 측정기를 갖추어야 한다. 또한 진정약제의 길항제를 반드시 구비해야 한다. 본 연구에서도 모든 병원에서 검사 전에 환자 상태를 파악하고 있었으며, 41개의 병원에서 ASA 점수를 기록하고 있었다. 진정약제 투여 전에 32개의 병원(64%)에서 산소 공급을 하고 있었다. 모든 병원에서 적어도 한 명 이상의 간호인력이 보조하였다. 모든 병원에서 의료인력에 대한 진정 교육을 시행하고 있었으며 학회에서 정기적으로 유지 보수 차원의 교육을 받고 있었다. 모든 병원에서 진정내시경 동안 산소 공급을 하고 있었고 산소포화도를 측정하였다. 진정내시경 동안 혈압측정은 37개 병원(74%)에서 이루어지고 있었으며, 심전도 모니터링은 23개 병원(46%)에서 이루어지고 있었다. 의식 수준의 평가는 44개의 병원(88%)에서 시행하였다. 모든 병원에서 검사실에 플루마제닐과 날록손 등의 진정 약물 길항제가 구비되어 있었다. 49개 병원(98%)에서 심폐소생술을 위한 장비가 구비되어 있었고, 진정내시경 관련 합병증은 37개 병원(74%)에서 기록하고 있었다. 모든 병원에서 회복실로부터의 퇴실지침을 구비하고 있었다. 진정내시경 관련 지표는 100% 이루어져야 하므로 향후 모든 병원에서 안전 지표가 개선되길 바란다.

2. 내시경 관련 합병증

내시경 관련 합병증으로 주로 알려진 것이 출혈, 천공, 흡인, 균혈증 등이다.

1) 천공

(1) 상부위장관내시경

진단적 상부위장관내시경 검사에서 천공이 되는 것은 매우 드물다. 약 0.02-0.2%로 보고되었다.[28] 천공은 주로 내시경 선단에 의한 기계적 점막손상에 의해 발생하며, 식도협착확장술과 같은 치료내시경 시에 더욱 빈도가 높게 발생한다. 상부식도의 이상와(pyriform sinus)와 Zenker게실, 윤상인두근(cricopharyngeal muscle)에서 천공이 잘 발생하나 가장 천공 빈도가 높은 부위는 하부 식도이다. 이 부위는 염증과 암이 잘 발생하는 부위로 병변에 의한 점막손상이 심할 수 있고, 식도 고유근층이 얇고, 위 후벽부가 심하게 굴곡되어 있거나 하면 내시경 진입 시에 손상을 쉽게 받을 수 있다. 또한 천공은 어느 부위던 조직학적으로 염증이 심하고, 무리한 내시경의 삽입 및 조작, 과도한 공기주입, 무리한 조직검사, 환자와 협조가 잘 되지 않는 경우에 주로 발생하며 천공으로 인한 사망률은 25%에 이르기 때문에 주의해서 내시경을 조작해야 한다. 식도 천공이 발생하였을 경우, 예후가 좋지 않으므로 치료는 대개 수술적 치료가 필요하다. 그러나 천공의 크기가 작고, 종격동의 염증소견이 없고, 활력증후가 안정적이고, 진행된 식도암의 천공이거나 즉각적으로 클립(clip) 치료를 시행할 수 있는 경우에는 클립 치료 후에 금식 및 항생제 투여, 비경구적 영양공급의 치료를 병행하면서 내과적으로 치료할 수도 있다. 진단 목적의 상부소화관내시경에서 위 천공은 매우 드물다. 천공 부위는 후벽을 따라 상부 체부에 잘 발생하며, 암 등의 병변이 있어 위벽이 약한 부위에서도 직접적인 기계적 손상으로 발생할 수 있다. 치료내시경으로 내시경 점막절제술 및 점막하 박리 절제술의 천공 발생률은 평균 1-8%로 보고되었다.[29,30] 주로 병변이 위의 상체부에 위치하고, 섬유화가

심하거나, 점막하층을 침범한 경우에 천공 발생의 빈도가 증가하였다. 본 연구에서는 2017년도 건강보험심사평가원의 청구자료와 2013-2017년까지의 50개 병원의 내시경 관련 합병증 빈도를 조사하였다. 2017년 진단 상부위장관내시경의 천공 빈도는 평균 0.023%로 서구 문헌과 비슷하게 매우 낮았다. 치료내시경의 천공 빈도는 평균 0.61%로 서구 보고보다 매우 낮았다. 의원급의 0.05%에 비해 종합병원에서 0.87%로 높았다. 50개 병원의 진단 상부위장관내시경의 천공 빈도는 0.0008%, 치료내시경은 평균 0.32%였다. 의원급에서는 내시경검사 도중 천공이 발생하게 되면 적절한 치료를 할 수 없는 경우가 많아 대개 상급종합병원으로 전원을 보내게 된다. 그래서 의원급에서는 천공의 빈도가 낮고 상급종합병원의 천공률이 더 높게 측정되었다. 청구자료 분석이기 때문에 정확한 종별 기관의 천공률은 알 수 없는 한계가 있었다.

(2) 결장경

진단적 목적의 결장경검사에서 천공의 빈도는 약 0.2%로 보고되었다.[31] 천공의 크기, 환자의 활력징후, 결장의 오염도, 천공을 진단할 때까지의 걸린 시간 등이 환자의 예후를 결정짓는 인자이다. 가장 흔한 천공 부위는 곧창자구불창자 경계 부위이며 그 다음은 막창자 부위였다. 진단 목적으로 시행하는 결장경검사에서 천공이 발생하는 기전은 세 가지로 정리할 수 있다. 첫째는 내시경 선단이 직접 점막을 뚫는 것으로 결장게실 부위나 협착이 심한 부위를 강제로 진입할 때, 항문을 보기 위해 무리해서 선단을 반전하는 경우 잘 발생한다. 내시경이 점막에 과근접이 되면 장벽이 내시경에 의해 밀려 돌출된 상태가 되며 점막색조는 적색이 되는데, 이때 더 내시경이 진행되면 백색으로 변하고 천공 직전상태가 된다. 급격한 조작을 하게 되면 이러한 단계적 변화를 인식하지 못한 채 순간적으로 천공이 일어나게 된다. 따라서 내시경의 조작을 처음부터 끝까지 신중히 하고, 내시경 선단이 항상 어느 부위에 위치해 있는가를 확인하고, 장관의 굴곡 방향을 확인하며 조작을 시행하고, 복잡한 굴곡 부위에서는 근접상이 되면 내시경을 빼내어 그

방향이 올바른지 확인한 후 다시 삽입을 시도해야 한다. 둘째는 내시경을 밀면서 내시경 측면과 점막의 마찰력으로 인해 발생하며, 셋째는 과도한 공기 주입으로 인해 천공이 되는 것이다. 폴립절제술과 관련된 천공 빈도는 약 0.3-0.4%로 1 cm 이상의 무경성용종의 용종절제술 때 천공이 잘 발생한다.[32] 얇은 결장벽 전 층을 올가미로 깊게 잡아 절제하는 경우와 전기 통전 시간이 과도하여 결장벽 전 층이 손상되어 발생하는 즉각적인 천공과 괴사조직에 의한 지연천공이 일어날 수 있다. 결장 천공으로 나타나는 증상은 지속적인 복통과 복부팽만이며 열과 백혈구증가증 등의 복막염 증세가 나중에 나타날 수 있다. 천공이 의심되는 경우, 흉부 또는 복부단순촬영에서 유리공기를 확인할 수 있고 천공 크기가 작아 유리공기를 확인할 수 없는 경우에는 복부컴퓨터단층촬영에서 진단할 수 있다. 치료는 천공 부위가 작고, 활력징후가 안정적이고, 결장 청소상태가 좋고, 복막염의 증거가 없을 경우 게실염과 마찬가지로 금식과 항생제 투여, 비경구적 영양공급과 같은 보존적 치료를 시도할 수 있다. 천공 부위를 즉시 확인할 수 있는 경우는 클립으로 천공 부위를 결찰하며 보존적 치료를 시도한다. 그러나 천공 부위가 크고, 오염이 심하고, 복막염의 증거가 명확하고 24-48시간 이내에 내과적 치료에 반응을 보이지 않고 통증이 지속되는 경우 수술적 치료가 필요하다. 본 연구에서 2017년도 진단 결장경의 천공 빈도는 평균 0.0065%였다. 의원급 0%에 비해 상급종합병원의 천공 빈도는 0.03%로 높았다. 치료 결장경의 천공 빈도는 0.01%였다. 의원급 0.004%에 비해 상급종합병원에서 0.06%로 높았다. 50개 병원에서 진단 결장경의 천공 빈도는 평균 0.014%, 치료내시경은 0.13%였다.

2) 출혈

(1) 상부위장관내시경

출혈은 진단 목적의 상부위장관내시경검사에서 매우 드물게 발생하는 합병증으로 대개 내시경이 통과하

면서 발생하는 선단의 기계적 자극과 관련이 있다. 출혈 빈도는 약 0.15%로 보고되었다.[33] 출혈의 위험은 이전에 위절제를 시행 받은 환자에게서 증가했으며 조직검사 후에 출혈 빈도는 0.8%로 보고되었다.[34] 아이러니하게도 아스피린이나 소염진통제를 복용하는 환자에서 내시경 및 조직검사로 인한 출혈 합병증의 빈도는 증가하지 않는 것으로 보고되었다. 또한 ASGE 연구에 따르면 혈소판 수가 20,000까지 감소하더라도 상부위장관내시경을 안전하게 시행할 수 있었으며 혈소판 수가 20,000 미만일 때에는 조직검사나 치료내시경이 꼭 필요한 경우 혈소판 수혈을 통해 혈소판 수를 20,000 이상 유지할 것을 권고하였다. 치료는 활동성 출혈이 관찰되거나, 혈관이 노출되어 있을 경우에 전기소작술, 에피네프린 주사요법, 클립지혈술 등의 내시경적 지혈술을 시행한다. 드물게 내시경적 지혈술에도 출혈이 계속되는 경우에는 혈관조영술에 의한 지혈이나 수술이 필요한 경우도 있다. 상부위장관내시경 시행 도중 과도한 트림이나 구역질 등으로 Mallory-Weiss 째짐이 발생할 수 있다. 발생 빈도는 약 0.07%로 보고되었다.[35] 대게 보존적 치료로 회복되나 드물게 활동성 출혈을 보이거나 혈관이 노출되어 있으면 내시경적 지혈술이나 혈관조영술, 수술이 필요할 수 있다. 치료내시경에서의 출혈 빈도는 4.6-15.6%로 보고되었다.[36] 위험인자는 병변이 상체부에 위치해 있을 때, 크기가 2 cm보다 크거나, 점막하층 침범, 항혈소판제 복용력이 있는 경우였다. 본 연구에서 2017년 진단 상부소화관내시경의 출혈 빈도는 평균 0.22%였다. 의원급 0.017%에 비해 상급종합병원에서 0.572%로 의미 있게 높았다. 치료내시경은 평균 3.16%였다. 의원급은 0.49%였고 종합병원에서 4.16%였다. 천공과 마찬가지로 서구 문헌에 비해 출혈 빈도는 낮았지만 상급종합병원으로 갈수록 의원급의 전원, 고위험군의 환자와 고난이도의 시술이 많기 때문인 것으로 사료된다. 50개 병원의 진단 상부소화관내시경의 출혈 빈도는 평균 0.013%, 치료내시경은 2.29%였다. 역시 서구 문헌보다는 낮게 분석되었다.

(2) 결장경

진단적 목적의 결장경검사에서 출혈 합병증의 빈도는 매우 낮아 약 0-0.07%로 보고되었다.[37] 조직검사 시 출혈의 빈도는 증가하여 0.3%, 폴립절제술 후에는 약 1.5-2%로 보고되었다. 출혈은 혈관이 잘 발달된 혈종이나 혈관이형성 부위에서 조직검사를 시행한 경우에 잘 발생한다. 조직검사 후에 발생하는 출혈은 대개 저절로 멎지만 반복적인 물세척에도 출혈되는 경우에는 내시경적 지혈술이 필요한 경우도 있다. 폴립절제술 시 일반적으로 절개파를 주로 사용한 경우는 즉각적인 출혈이 잘 발생하며 응고파를 주로 이용한 경우는 천공이나 지연 출혈이 잘 발생한다. 지연 출혈은 매우 드물지만 전기 응고 과다에 의한 조직 괴사로 심층의 혈관이 노출되어 출혈하는 것이다. 폴립절제술 후 2일부터 15일째까지 발생하는데 때로는 4주 후에 발생한 경우도 있었다. 폴립절제술 후에 출혈이 의심될 경우, 활력징후가 안정적이고 헤마토크리트가 정상이면 조심스럽게 경과관찰을 하며, 분명한 혈변을 보이거나 헤모글로빈이 2 이상 감소한 경우에는 결장내시경을 시행하여야 한다. 병변에서 혈관이 노출되어 있거나 활동성 출혈이 관찰될 경우에는 전기소작술, 에피네프린 주사요법, 클립지혈술 등의 내시경적 지혈술을 시행하며, 드물게 내시경적 지혈술에도 출혈이 계속되는 경우에는 혈관조영술에 의한 지혈이나 수술이 필요한 경우도 있다. 본 연구에서 2017년도 진단 결장경의 평균 출혈 빈도는 0.198%였다. 의원급은 0.129%, 상급종합병원은 0.475%로 상급종합병원에서 출혈의 빈도가 높았다. 치료내시경의 평균 출혈 빈도는 0.356%였다. 의원급은 0.258%, 상급종합병원은 0.730%였다. 50개 병원의 평균 진단 결장경의 출혈 빈도는 0.022%, 치료내시경은 0.451%였다. 모두 서구 보고에 비하면 낮은 결과를 보였다.

3. 안전 지표

2017년 청구자료와 5년간의 50개 병원의 내시경 건수, 실태 조사를 통해 안전한 내시경실 환경을 구축하기 위한 지표를 선정하였다. 필수항목과 권고항목으로 나누어 의원급 및 병원급에서도 적용할 수 있는 지표를 제시하였다.

1) 구조지표

내시경실의 구성, 검사실 필요 장비, 회복실 필요 장비, 세척실 환경은 안전한 내시경실을 만들기 위해 비교적 쉽게 구축할 수 있는 지표이다. 다양한 환자군에서 내시경검사가 이루어지므로 고위험군의 환자에서는 진정내시경을 시행하지 않더라도 산소 공급, 활력증후의 체크가 필요할 수 있다. 또한 진정내시경 중 급작스럽 호흡저하로 심폐소생술을 시행하는 경우가 종종 발생하므로 심폐소생술 장비는 반드시 갖추어야 한다. 오염구역과 청결구역을 구분해야 하는 세척실 환경은 쉽게 고칠 수 있는 것이 아니므로, 내시경실 리모델링 시 꼭 고려해야할 사안이다.

(1) 적절한 검사실 수, 적절한 근무 인력

현재 많은 의료기관에서 검사실, 의료인력에 비해 과도하게 많은 내시경검사를 시행하고 있다. 낮은 내시경 수가에 기인한 바 크지만, 이로 인해 오진율과 합병증 발생의 증가는 필연적이다. 상부소화관내시경의 이상적인 검사 시간에 대해서는 잘 알려져 있지 않다. 최근 연구에서 3분 이상 상부소화관내시경을 시행한 군이 3분 미만으로 관찰한 군에 비해서 의미 있게 식도병변을 더 잘 관찰하였다는 보고를 하였다.[38] 그러나 실제로는 3분도 매우 짧은 검사 시간으로, 조직검사를 한다면 5분을 넘기는 경우가 대부분이다. 또한 내시경검사 전과 후에 환자의 기록과 안내 등의 추가 시간까지 고려한다면 한 시간에 한 검사실에서 상부위장관내시경을 2-3개 시행하기도 어렵다. 그러므로 한 기관에서 검사실, 인력 대비 적절한 내시

경검사의 건수는 안전한 환경을 위해 필수적이다. 많은 검사를 하기 위해서는 검사실, 장비의 확충과 인력의 보강이 반드시 필요하다. 또한 검사실마다 의사와 간호사는 1명이상 상주해야 하며, 복잡하거나 시간이 오래 걸리는 치료내시경을 하는 동안에는 간호인력이 2명이상 필요하다. 표 13에서 보듯이 간호인력, 의사, 검사실의 수는 내시경 합병증과 연관된 중요한 인자이다. 각 기관마다 적절한 내시경검사 수, 의료인력, 간호인력, 검사실의 수는 내시경실 안전 지표에 핵심이다.

(2) 유지 및 보수, 내시경세부전문의 비율

국가에서 공식으로 인정한 전문의는 아니지만 내시경 관련 학회에서 일정한 수준 이상의 내시경의의 자격을 인정한 것이 내시경인증의이다. 각 학회에서 일정한 건수 이상을 시행하였는지 조사하고 시험을 통해 전문 지식을 측정하여 자격을 부여한다. 세부전문의가 아니더라도 매년 전문학회로부터 교육을 받는다면 실력을 인정받을 수 있을 것이다. 경험이 풍부하고 실력 있는 의료진이 검사를 한다면 합병증의 발생을 줄일 수 있는 것은 자명한 일이다. 향후 많은 연구를 통해 전문가의 비중을 어느 정도 높일 수 있는 지표가 제시되길 기대한다.

(3) 검사실 당 회복실 침상 비율, 회복실의 적절한 간호인력

검사실 당 회복실 침상 비율은 2 이상 권고되고 있으며,[13] 설문조사에서도 대부분의 병원에서 지표를 만족하고 있었다. 회복실의 적절한 간호인력은 48%의 병원에서 1:10 미만이었고, 회복실에서 근무하는 간호사도 1명 당 10명 미만의 환자를 간호하길 희망하였다. 진정내시경 후에 안전하게 환자의 회복을 돌보는 것은 매우 중요한 일로, 안전사고 예방에 필수적이다. 현재 반 이상의 상급종합병원에서도 간호사 1명 당 10명 이상의 환자를 간호하는 것이 현실이므로, 향후 의원급이나 병원급에서 적절한 간호인력의 확충

이 필요할 것으로 사료된다.

2) 과정지표

안전한 내시경검사를 위해서는 내시경 전에 환자의 병력, 약물 복용력, 과거력을 파악하는 것이 중요하다. 많은 인력과 시간이 필요한 작업으로 적지 않은 의료기관에서 간과하고 있는 지표들이다. 국가암 검진 분야에서도 간호사와 의사가 환자를 파악하고 기록하는 서류가 일원화되지 않아 많은 지적이 있었던 부분이다. 이에 대한소화기내시경학회에서는 안전한 내시경검사를 위해 상부위장관내시경, 결장경검사의 동의서, 설명서, 사전점검표를 표준화하여 배포하였다. 본 연구에서도 안전한 내시경검사를 위해 내시경 전 환자 평가, 내시경 도중에 환자 평가, 내시경 후에 환자 평가 및 설명의 전 과정을 안전하게 진행할 수 있도록 지표를 구성하였다. 거의 빠짐없이 이루어져야 하는 과정이므로 100% 달성을 목표로 한다. 또한 중요한 것이 의원급과 병원급에서 점수가 낮은 항목이 고수준 소독제의 사용이다. 설문조사 결과 모든 병원에서 고수준 소독제를 사용하고 있었지만 의원급으로 갈수록 지켜지지 않는 지표이므로 반드시 교육과 평가를 통해 감염의 빈도를 줄이도록 노력해야 한다.

3) 결과지표

내시경과 관련된 안전사고와 합병증이 발생하였을 경우에 의료기관에서는 의료사고의 경우를 염두에 두어 발생을 신고하지 않는 경향이 많았다. 최근에 병원인증평가의 강화와 여러 질 평가 시행 등으로 각 기관마다 합병증 발생을 공식적으로 기록하기 시작하였다. 안전사고 및 합병증 발생 시 대처에 미흡한 점이 없었는지 분석하고 보고함으로써 재발 방지에 큰 도움이 될 것으로 생각한다. 본 연구에서도 청구자료와 설문조사의 합병증 발생 빈도가 매우 낮게 관찰되었다. 상당수의 합병증이 누락되었을 가능성이 많

으며, 향후 지속적인 관리와 평가로 정확한 데이터가 축적이 될 것으로 생각한다. 안전사고와 합병증 발생과 관련된 지표는 100% 수행을 목표로 해야 한다.

4. 연구의 한계 및 향후 연구 과제

본 연구는 2017년도 건강보험심사평가원의 청구자료와 우리나라를 대표하는 50개 종합병원과 상급종합병원의 5년간의 내시경자료를 분석하였다. 매우 많은 자료라서 개개인의 상황을 정확히 분석하지 못해 인과 관계를 정확히 예측할 수 없는 한계를 지닌다. 또한 최근에나 상급종합병원을 대상으로 내시경의 합병증을 조사하고 기록하였지, 과거에는 합병증 발생이 민원의 소지가 되기 때문에 노출을 꺼렸다. 그러므로 상당한 건수의 합병증 발생이 누락되었을 가능성이 있다. 이러한 요소가 통계를 분석하는 데에 있어 신뢰성을 떨어뜨릴 것으로 생각한다.

표 5에서 보듯이 의원급에서 가장 많은 비중의 진단 상부소화관내시경, 진단 결장경, 치료 결장경을 시행하고 있으며 거의 무시해도 될 정도의 합병증 발생 빈도를 보였다. 가장 많은 내시경을 매우 안전하게 시행하고 있는 것으로 오인될 수 있다. 의원급에서 내시경 도중 천공이나 출혈, 호흡곤란이 발생하게 되면 상급종합병원으로 전원을 보낸다. 합병증 발생 상병이나 치료 청구가 의원급에서는 누락이 되고, 상급종합병원에서 발생한 합병증으로 많은 건수가 옮겨 가기 때문에 절대적인 수치로 해석할 수 없는 단점이 있다. 이것 또한 본 연구의 한계로 커다란 통계적 오류의 발생을 부인할 수 없다. 추후에 같은 환자의 재치료율, 입원 발생 등까지 고려한 조작적 정의를 설정하고 분석하여 종별로 정확한 합병증 발생 빈도를 분석하는 것이 중요하겠다. 이와 유사하게 결장경에서 폴립절제술의 빈도 또한 오류를 유발하였다. 폴립이 다수 발견되면 의원급에서 모두 제거하지 못하고 한 두 개만 제거하거나 조직검사를 시행하고 상급병

원으로 전원을 보내게 된다. 이중 청구 문제로 상당히 많은 환자에서 폴립절제술의 청구가 중복이 되었을 가능성이 높다. 의원급에서 가장 많은 건수의 결장경을 시행하였지만 폴립절제술의 건수가 많은 것은 부풀려진 결과이며, 완전한 제거 및 치료의 의미가 아니라 조직검사로서의 의미가 클 것으로 사료된다.

또 다른 연구의 한계점은 안전 지표를 적용할 수 있는 범주가 큰 병원에 치중되어 있다는 점이다. 국가암 검진 내시경 분야의 지표나 우수내시경실 인증제 지표 모두 상급종합병원에서 근무하는 대한소화기내시경학회 소속의 교수가 제작한 것이다. 내시경에 관한 최고의 전문가지만 근무 환경이 상급종합병원으로 의원급의 현실을 자세히 알지 못한다는 점이다. 설문조사 또한 종합병원과 상급종합병원의 실태를 조사한 것으로 의원급이나 병원급의 실태를 정확하게 알기 어렵다. 안전 지표가 상급종합병원의 실태를 근거로 제시되었기 때문에 의원급에 하향하여 적용하기에는 현실을 반영하지 못한 지표가 될 가능성이 높다. 추후에 국가 암검진평가를 기반으로 건강보험관리공단과 연계하여 의원급, 병원급 기관의 실태를 조사하여 분석함으로써 보다 현실을 반영하는 지표를 제시해야할 것이다.

마지막으로 본 연구에서는 성과지표를 제시하지는 못하였다. 2018년 국가 암검진평가의 내시경 분야에서는 맹장삽입률, 장정결도를 처음으로 조사하기 시작하였다. 검사의 오류로 병변을 놓치는 것은 생명과 관련 있는 것으로 멀리 보면 안전과 관련된 중요한 지표이다. 서구에서 제시하는 맹장삽입률, 장정결도 95%, 선종발견율 40%는 상급종합병원에서도 아직 달성하기 힘든 지표이다. 향후 지속적인 노력과 평가는 이상적인 지표에 다다를 것으로 사료되면 추가 연구를 통해 안전과 관련된 성과지표에 대한 분석도 필요할 것으로 사료된다.

그럼에도 불구하고 50개 병원에서의 5년간의 내시경 관련 합병증 빈도와 병원의 환경을 조사한 것은 국내 최초의 연구로 기여하는 바가 크다. 빅데이터를 바탕으로 한 연구는 대부분 결장경과 관련 있는 연구

였지만, 본 연구에서는 조작적 정의를 통해 상부위장관내시경의 합병증 빈도를 최초로 조사하였다. 정확하지는 않았지만 향후 여러 연구가 진행될 경우에 본 연구 결과가 기본 결과로 비교의 대상이 될 것으로 생각된다. 또한 통계에 입각하여 최초로 적절한 검사실의 수, 검사실 근무 인력의 수를 분석함으로써 안전한 내시경 환경의 구조적인 조건을 제시하였다는 점이다. 추후에 기관마다 실제로 시행한 내시경검사 수를 바탕으로 이상적인 검사실, 의료인의 수를 보완할 수 있을 것이며, 안전한 내시경실을 평가하는 기준이 될 것이다. 또한 이것을 기초로 적절한 내시경 수가를 산정하는 데에 도움이 될 것으로 생각한다. 이상을 종합해 보면, 각 기관에서는 시행하는 검사 건수에 맞게 적절한 인력과 검사실을 갖추고 규격화된 지침에 맞게 검사를 시행하며, 안전사고 및 합병증 발생 시 신속히 대처하고 치료해야 한다. 안전한 내시경실 환경을 구축하기 위해서 안전사고와 합병증의 발생을 분석하고 재발을 방지하는 것이 중요하겠다. 이를 위해 지속적인 평가와 적절한 수가의 산정은 필수적이다.

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부록 1: 설문자료

2018 내시경실 질관리 Survey 항목

**해당하는 부분에 v 표시 해주세요*

1. 기본정보

1) 귀하가 근무하는 병원의 규모는 어떻게 됩니까?

□의원, □병원, □종합병원, □상급종합병원, □검진센터, □기타 ( )

2) 귀하가 근무하는 병원의 위치는 어떻게 됩니까?

□서울, □부산, □인천, □대전, □광주, □대구, □울산, □경기, □강원, □충청, □전라, □경상,

□제주, □기타 ( )

2. 인력현황

1) 현재 내시경실에 근무하는 내시경 시행 의사는 몇 명입니까? ( )명

: 그중 소화기내시경세부전문의는 몇 명입니까? ( )명

: 그중 내시경인증의는[1] 몇 명입니까? ( )명

[1] 대한소화기내시경학회 이외의 단체에서 인증하는 내시경의사 자격증

2) 현재 내시경실에 근무하는 간호사는 몇 명입니까? ( )명

3) 현재 내시경실에 근무하는 간호조무사는 몇 명입니까? ( )명

4) 현재 내시경실에 근무하는 보조인력은 몇 명입니까? ( )명

3. 시설현황

1) 내시경 검사실의 개수는 어떻게 됩니까?

: 전체 검사실 ( )개, 시술 전용(치료내시경) 검사실 ( )개

2) 각 검사실의 평균 넓이는 어떻게 됩니까? ( ) m^2

3) 검사실과 분리된 회복실이 있습니까? □ 예 □ 아니요

3.1) 회복실의 넓이는 어떻게 됩니까? ( ) m^2

3.2) 회복실의 침상 수는 몇 개입니까? ( )개

3.3) 회복실 침상에서 산소 공급이 가능합니까? □ 예 □ 아니요

4) 회복실 전담 간호인력이 있습니까? □ 예 □ 아니요

5) 회복실 전담 간호인력은 몇 명입니까?

□ 간호사 ( )명

□ 간호조무사 ( )명

□ 기타 보조인력 (　　)명

6) 회복실 전담인력(간호인력):환자 비율은 어느 정도 됩니까?

① 1:10 미만

② 1:10~1:15

③ 1:15~1:30

④ 1:30 초과

6.1) 귀하께서 적당하다고 생각하시는 회복실 전담인력:환자 비율은 어느 정도입니까?

① 1:10 미만

② 1:10~1:15

③ 1:15~1:30

④ 1:30 초과

7) 회복실의 침상 수:환자 비율은 어느 정도입니까?

① 1:10 미만

② 1:10~1:15

③ 1:15~1:30

④ 1:30 초과

7.1) 귀하께서 적당하다고 생각하시는 침상 수:환자 비율은 어느 정도입니까?

① 1:10 미만

② 1:10~1:15

③ 1:15~1:30

④ 1:30 초과

8) **회복실**의 모든 침상마다 심전도/혈압/산소포화도 모니터링 시설을 구비하고 있습니까?

☐ 예 ☐ 아니요

8.1) 모두 구비되어 있지 않다면 각각 몇 개의 모니터링 시설이 있습니까?

☐ 심전도 ( )개

☐ 혈압 ( )개

☐ 산소포화도 ( )개

9) 내시경 **검사실**의 모든 침상마다 심전도/혈압/산소포화도 모니터링 시설을 구비하고 있습니까?

☐ 예 ☐ 아니요

9.1) 모두 구비되어 있지 않다면 각각 몇 개의 모니터링 시설이 있습니까?

☐ 심전도 ( )개

☐ 혈압 ( )개

☐ 산소포화도 (　　)개

10) 내시경 및 본체에 대한 정기 검사 장부, 수리 장부 및 기록이 있습니까? ☐ 예　☐ 아니요

11) 각 검사실 마다 적절한 환기시설이 있습니까? ☐ 예　☐ 아니요

12) 내시경실 내에 유사시(환자 이송용) 사용할 수 있는 휴대용 산소 탱크가 몇 개 있습니까?

☐ 없음　☐ 있음 (개수:　　)

13) 내시경 검사실에 이산화탄소를 이용하는 송기 시스템이 있습니까? ☐ 예　☐ 아니요

14) 내시경 검사실 사이를 구분된 방이 아닌 칸막이나 커튼으로 구분하고 있습니까?

☐ 방 구분이 있음

☐ 칸막이나 커튼으로 구분

15) 환자 탈의실이 성별에 따라 분리되어 운영되고 있습니까? ☐ 예　☐ 아니요

16) 내시경센터 내에 화장실이 있습니까? ☐ 예　☐ 아니요

17) 내시경센터 내에 검사 전 환자가 대기할 수 있는 공간이 있습니까?

☐ 없음　☐ 있음 (좌석 수:　　개)

18) 새로운 내시경 장비 및 기기에 대한 교육 프로그램이 있습니까? ☐ 예　☐ 아니요

4. 성과지표

1) 2013년부터 2017년까지(5년간) 시행한 내시경 건수가 어떻게 됩니까?

년도		2013	2014	2015	2016	2017	합계
일반							
위내시경	진정						
	비진정						
대장내시경	진정						
	비진정						
치료내시경							
위내시경	ESD						
	EMR						
	Polypectomy						
대장내시경	Polypectomy						
	EMR						
	ESD						

2) 내시경 결과보고서에 검사 관련 합병증을 기록합니까? □ 예 □ 아니요

3) 내시경 결과보고서에 **위내시경** 시술 시간을 기록합니까? □ 예 □ 아니요

4) 내시경 결과보고서에 피검자의 주요 병력(고혈압, 당뇨, 심장질환 등)을 기록합니까?

□ 예 □ 아니요

5) 내시경 결과보고서에 피검자의 약제 복용력(항혈전제 등)을 기록합니까? □ 예 □ 아니요

6) **대장내시경** 검사 시 회수 시간을 기록합니까? □ 예 □ 아니요

6.1) 기록한다면 최근 1개월간 평균 6분 이상 회수 시간을 기록한 대장내시경검사의 비율은 얼마입니까? ( )%

7) 대장내시경 시 맹장삽관율을 기록합니까? □ 예 □ 아니요

7.1) 기록한다면 가장 최근 조사된 맹장삽관율은 얼마입니까? ( )%

8) 용종발견율(polyp detection rate)을 주기적으로 측정합니까? □ 예 □ 아니요

8.1) 측정한다면 가장 최근 측정치는 얼마입니까? ( )%

9) 선종발견율(adenoma detection rate)을 주기적으로 측정합니까? □ 예 □ 아니요

9.1) 측정한다면 가장 최근 측정치는 얼마입니까? ( )%

10) 최근 일년간 대장내시경검사의 대장정결 정도가 "적절" 이상인 경우가 대략 ( )% 입니까?

11) 내시경 관련 합병증 발생 건수에 대한 월별(연도별) 통계가 있습니까? □ 예 □ 아니요

12) 지난 5년간 내시경 관련 합병증 발생 건수가 어떻게 됩니까?

			2013	2014	2015	2016	2017
출혈	위	진단[2]					
		치료[3]					
	대장	진단					
		치료					
천공	위	진단					
		치료					
	대장	진단					
		치료					
진정사고 (혈압저하/호흡저하 등)							
낙상							
사망							
기타 안전사고							

[2] 진단내시경 후 발생

[3] 치료내시경 후 발생

5. 소독

1) 내시경 전세척 과정에 무엇을 사용하십니까?

☐ 멸균수

☐ 효소세정제

1.1) 효소세정제를 사용하신다면, 현재 사용 중인 세척제(효소제정제)는 무엇입니까?

( )

2) 현재 사용 중인 소독제는 무엇인가요? (중복 가능)

☐ 글루탈알데하이드

☐ 올소-프탈알데하이드(OPA)

☐ 과초산

☐ 전해산성수

☐ 기타 ( )

3) 현재 근무 중인 소독 전담요원이 있습니까? ☐ 예 ☐ 아니요

3.1) 소독 전담요원의 자격과 인원은 어떻게 됩니까?

☐ 간호사 ( )명

☐ 간호조무사 ( )명

□ 기타 보조인력 (　　)명

3.2) 소독 전담요원은 몇 명이 적정 인원이라고 생각하십니까?

□ 1일 검사 건수 기준 100건 당 (　　) 명

4) 검사실과 분리된 세척실이 있습니까?

□ 방 구분이 있음

□ 칸막이나 커튼으로 구분

□ 분리된 소독실이 없음

5) 소독실에 적절한 환기시설이 있습니까? □ 예　□ 아니요

5.1) 아래 해당하는 항목에 표시해 주십시요.

□ 환기 후드

□ 환기 창

□ 기타: (　　)

6) 검사에 사용된 내시경을 전용상자 또는 바구니에 넣어 세척실로 이동합니까? □ 예 □ 아니요

7) 내시경을 세척하는 공간이 오염구역과 청결구역으로 구분되어 있습니까?

□ 방 구분이 있음

□ 칸막이나 커튼으로 구분

☐ 분리되어 있지 않음

8) 검사실과 세척실 간의 내시경 이동이 세척 전에는 오염통로, 세척 후에는 청결통로로 별도로 구분된 통로를 이용하여 이루어집니까? ☐ 예 ☐ 아니요

9) 세척에는 어떤 솔을 사용하십니까?

☐ 1회용 솔을 1회만 사용

☐ 1회용 솔을 소독하여 재사용

☐ 재사용 가능한 솔을 소독하여 재사용

10) 소독 후 헹굼 과정에는 어떤 물을 사용하십니까?

☐ 필터로 여과한 물 혹은 멸균된 물

☐ 필터로 여과하지는 않았지만 마실 수 있는 정도의 물

☐ 수돗물

11) 자동소독기를 보유하고 있습니까?

☐ 예 (소독기 수: 개)

☐ 없음

12) 내시경 소독의 정도 관리를 위한 균배양검사 지침이 마련되어 있습니까? ☐ 예 ☐ 아니요

13) 내시경 소독의 정도 관리를 위해 균배양검사를 시행하십니까?

☐ 전혀 시행하지 않음

☐ 필요하다고 판단될 때만 비정기적으로 시행

☐ 정기적으로 시행 (☐ 연 1회, ☐ 연 2회, ☐ 연 3회, ☐ 연 4회 이상)

14) 고수준 소독제의 최소유효농도를 확인하고 있습니까?

☐ 확인하지 않음

☐ 매일 검사 시작 전 1회 확인

☐ 매일 검사 시작 전과 소독제 교체 시기를 전 후로 여러 차례 반복 시행

15) 고수준 소독제의 교체 시기는 어떻게 결정하고 있습니까?

☐ 소독 횟수에 관계없이 매일 아침 교체

☐ 소독 횟수에 따라 교체

☐ 최소유효농도를 스트립으로 직접 확인 후 교체

16) 현재 소독 근무자가 세척 동안 착용하고 있는 개인보호장비를 모두 선택해 주세요.

☐ 보호 마스크

☐ 보호 모자

☐ 방수 가운

☐ (고무)장갑

☐ 고글

☐ 앞이 막혀있는 신발

☐ 귀마개

☐ 기타 ( )

17) 소독실무자(면허 있는 간호인력 제외)는 소독 교육을 시행받았습니까? ☐ 예 ☐ 아니요

17.1) 소독실무자의 소독 교육은 어디에서 받았습니까?

☐ 대한소화기내시경학회 또는 지회 소독 교육

☐ 대한간호협회/대한소화기내시경간호학회 본회 또는 지회 소독 교육

☐ 지역암센터(국립암센터 주관) 중심 소독 교육

☐ 대한위대장내시경학회 및 지회 소독 교육

☐ 기타(상기 이외의 학회/협회 주관 교육 또는 원내 교육): _____

18) 귀 기관에서 어떤 소독지침서를 사용하고 있습니까?

☐ 대한소화기내시경학회 내시경 세척 및 소독지침

☐ 개원의를 위한 내시경 세척 및 소독지침

☐ 원내 소독지침

☐ 기타: _____

6. 진정

1) 귀하께서는 상부진정내시경(진단) 시에 어떤 약제를 사용하십니까?

(1) 진정제

① 미다졸람(midazolam)

② 프로포폴(propofol)

③ 미다졸람 + 프로포폴 병합

④ 기타(에토미데이트 등): _____

(2) 진통제

① 투여 안 함

② 메페리딘

③ 펜타닐

④ 기타: _____

2) 진정내시경검사 전 평가로 미국 마취과학회(American Society of Anesthesiologist, ASA) 분류에 따라 판단하고 기록하십니까? □ 예 □ 아니요

2.1) 얼마나 많은 환자에서 ASA 분류평가를 하고 계십니까?

① <1/4

② 1/4~1/2

③ 1/2~3/4

④ >3/4

3) 진정내시경 시술 전 평가로서 Mallampati score를 확인하고 기록하십니까? □ 예 □ 아니요

3.1) Mallapati score 평가를 얼마나 많은 환자에서 하고 계십니까?

① <1/4

② 1/4~1/2

③ 1/2~3/4

④ >3/4

4) 진정 약제 투여 전에 사전 산소 공급을 하십니까? □ 예 □ 아니요

4.1) 언제부터 산소 공급을 시작하십니까?

① 내시경검사 직전

② 내시경검사 1-5분 전

③ 내시경검사 5-15분 전

④ 내시경검사 15-30분 전

5) 진정내시경검사 중 진정 유도 약제의 종류, 초기 용량, 추가 용량, 투여 간격 등을 누가 결정합니까?

① 내시경의사

② 내시경시술보조의사(비마취과)

③ 마취과의사

④ 진정 교육을 받은 간호사

⑤ 기타(진정 교육을 받지 않은 간호사, 간호조무사, 단순 보조인력 등): _____

6) 진단을 위한 진정내시경검사 동안에 내시경의사 외에 몇 명의 **보조인력**이 참여합니까?

① 추가 인력 없음

② 간호인력 1명

③ 간호인력 2명 이상

④ 기타(의사, 단순 보조인력 등): _____

7) 보조인력이 진정 교육을 시행 받았습니까? □ 예 □ 아니요

7.1) 보조인력의 진정 교육은 어디에서 받았습니까?

① 대한의사협회 주관 프로포폴 진정 교육

② 대한소화기내시경학회 세미나 또는 지회 연수강좌 진정 세션

③ 대한간호협회/대한소화기내시경간호학회 본회 또는 지회 주관 진정 교육

④ 기타(상기 이외의 학회/협회 주관 교육 또는 원내 교육): _____

8) 진정내시경검사 중 산소포화도 모니터링을 하십니까? □ 예 □ 아니요

9) 진정내시경검사 중 저산소증 발생시 산소 공급을 하십니까? □ 예 □ 아니요

10) 진정내시경검사 중 정기적으로 혈압측정을 하는 환자의 비율이 얼마나 됩니까?

① <1/4

② 1/4~1/2

③ 1/2~3/4

④ >3/4

11) 진정내시경검사 중 심전도를 모니터링하는 환자의 비율이 얼마나 됩니까?

① <1/4

② 1/4~1/2

③ 1/2~3/4

④ >3/4

12) 진정내시경검사 중 의식 수준을 평가하는 환자의 비율이 얼마나 됩니까?

① <1/4

② 1/4~1/2

③ 1/2~3/4

④ >3/4

13) 검사 후 회복실에서 생체 징후를 어느 간격으로 확인하십니까?

☐ 맥박수: ( ) 분

☐ 혈압: ( )분

☐ 호흡수: ( )분

☐ 의식 수준: ( )분

14) 역설반응 발생 시에 어떻게 대처하십니까?

① 같은 진정제를 더 투여한다.

② 다른 진정제를 추가 투여한다.

③ 길항제 등을 통해 회복 후 비진정 상태에서 검사한다.

④ 기타:

15) 검사실에 플루마제닐(flumazenil)과 날록손(naloxone) 등의 진정약물 길항제가 구비되어 있습니까? ☐ 예 ☐ 아니요

16) 진정내시경검사 시 길항제를 얼마나 자주 사용하십니까?

① <1/4

② 1/4~1/2

③ 1/2~3/4

④ >3/4

17) 진정내시경검사 시 어떠한 경우에 길항제를 주로 사용하십니까?

① 상시 사용

② 저산소증

③ 역설반응

④ 기타:

18) 검사실에 심폐소생술을 위한 장비가 구비되어 있습니까? □ 예 □ 아니요

19) 최근 1년 이상 동안 발생한 진정내시경 관련 합병증을 기록하는 문서 및 장부가 보관되어 있습니까? □ 예 □ 아니요

20) 진정내시경 후 퇴실할 때 보호자가 동반하도록 권고하십니까? □ 예 □ 아니요

부록 2: 추가 설문자료

2. 인력현황

6) 내시경 근무 인력(의사, 간호인력, 보조인력)에 대한 내시경 관련 교육 규정이 있습니까?

☐ 예 ☐ 아니요

6.1) 내시경 수기 ☐ 예 ☐ 아니요

6.2) 내시경 시술 보조 ☐ 예 ☐ 아니요

6.3) 진정 ☐ 예 ☐ 아니요

6.4) 소독 ☐ 예 ☐ 아니요

3. 시설현황

1) 내시경실 내 온도와 습도를 매일 정기적으로 체크합니까? ☐ 예 ☐ 아니요

2) 검사 시행 전에 성명 및 생년월일을 확인하는 등 환자 확인 절차가 있거나 시행합니까?

☐ 예 ☐ 아니요

5) 검사실 내에 산소 공급 장치와 흡입 장치가 설치되어 있습니까? ☐ 예 ☐ 아니요

10) 내시경실 안의 공간(검사실 및 세척실 등) 마다 착용하는 의료인의 복장 및 개인보호장비 착용 및 탈의에 대한 규정이 있습니까? ☐ 예 ☐ 아니요

11) 검사실 내에서 개인보호장비를 착용합니까? ☐ 예 ☐ 아니요

11.1) 현재 검사실 내에서 의료진이 착용하고 있는 개인보호장비를 모두 선택해 주세요.

☐ 보호 마스크

☐ 보호 모자

☐ 방수 가운

☐ 장갑

☐ 고글

☐ 앞이 막혀있는 신발

☐ 기타 ( )

24) 주사약제를 준비 또는 조제하거나 보관하는 독립된 준비실이 따로 있습니까?

☐ 예 ☐ 아니요

26) 내시경실 내에 직원 및 환자를 대상으로 교육할 수 있는 독립된 공간이 있습니까(회의실 등)?

☐ 예 ☐ 아니요

26.1) 내시경실 외부에 직원 및 환자를 대상으로 교육할 수 있는 독립된 공간이 있습니까(회의실 등)? ☐ 예 ☐ 아니요

5. 감염

1) 올바른 손 씻기에 대한 규정(방법, 언제)이 있습니까? ☐ 예 ☐ 아니요

2) 주사약제의 보관 및 관리, 투여, 폐기(1회용 주사기 등 정맥 투여, 라벨)에 대한 관리 규정이 있습니까? ☐ 예 ☐ 아니요

3) 일회용 기구와 재사용 기구에 대한 관리 규정이 있습니까? ☐ 예 ☐ 아니요

4) 내시경검사 중에 사용하는 윤활젤리, 거즈 및 내시경을 통해 환자에 투여되는 물, 색소, 가스 및 거품제거제의 조제 및 보관, 폐기 등 사용 및 관리에 대한 규정이 있습니까?

☐ 예 ☐ 아니요

5) 검사실을 포함한 내시경실 환경에 대한 청결 및 소독에 대한 지침이 있습니까?

☐ 예 ☐ 아니요

4.1) 일과 시작 전에 검사실과 세척실을 청소합니까? ☐ 예 ☐ 아니요

4.2) 일과 종료 후에 검사실과 세척실을 청소 및 소독합니까? ☐ 예 ☐ 아니요

4.3) 소독은 무엇으로 하십니까?

☐ 세정제

☐ 소독제

☐ 세정제 + 소독제

☐ 기타 ( )

부록 3. 사전점검표/진정기록지

사전점검표/진정기록지

등록번호		검사일	20 년 월 일
성명	(□외래 □병실)	성별/생년월일	/
		키/몸무게	cm/ kg
시술명	□ EGD □Colonoscopy □ 기타 ( )		

금식여부	□예 □아니오(유동식/고형식)	진정평가	
치아확인	□양호 □치아 흔들림 □의치 제거	동의서 유무	□예 □아니오
보호자 동반 유무	□예 □아니오		
전신상태	□ 양호 □ 만성병색 □ 급성병색 □ 열	투여약물	Midazolam ( ) mg, Propofol ( ) mg, Pethidine ( ) mg, Fentanyl ( ) ml
장정결	□ 시행함 □ 시행안함 □관장	기타약제	
병력		활력징후	검사전 혈압:(/), 맥박:( ), 호흡수:( )
① 경부 및 복부 수술력 (후두, 인두 포함)	□ 예		검사후 혈압:(/), 맥박:( ), 호흡수:( )
('예의 경우 구체적 기술)		진정평가	□ 최소 □ 중증도 □ 깊은진정
② 고혈압	□ 예		□ 수면유도 안됨
③ 심혈관계질환 : 심부전 또는 심내막염 등의 병력, 인공판막/심박동기 삽입 여부	□ 예		□ 기타
④ 대뇌질환 : 중풍, 뇌출혈	□ 예	SpO2	검사중: ( )-( )%
⑤ 호흡기질환 : 천식, 만성폐쇄성기관지질환 등	□ 예		회복중: ( )-( )%
⑥ 출혈경향 질환	□ 예	산소공급	□아니오 □예: ( ) liter
⑦ 만성콩팥병	□ 예	퇴실기준	Aldrete Score 9점 이상 또는 시술 전 상태와 동일하게 회복 □ 예
⑧ 간경변	□ 예		
⑨ 당뇨	□ 예		
⑩ 알레르기	□ 예		
('예의 경우 구체적 기술)			
⑪ 기타 : 녹내장, 전립선비대 등	□ 예		
('예의 경우 구체적 기술)			
현재 복용중인 약물			
① 항혈소판제/항응고제	□ 예		
□ 아스피린 □ 클로피도그렐 □ 기타 ( )			
□ 항응고제 (약품명:)			
상기 약물 복용을 중지하였습니까?	일전 /아니요		
② 인슐린/경구혈당강하제	□ 예		
④ 항우울제/진정제	□ 예	참고사항	
⑤ 기타약제		기록자	

Adult Post procedure/Post sedation Recovery Score (Aldrete Score)		점수
운동능력	명령 또는 자발적으로 모든 팔다리 운동 가능	2
	명령 또는 자발적으로 2개의 팔다리 운동 가능	1
	자발적으로 모든 팔다리 운동 불가능	0
호흡	심호흡 및 기침 가능	2
	호흡 곤란 또는 호흡 운동 제한	1
	무호흡	0
순환	마취-진정 전 혈압의 ±20%	2
	마취-진정 전 혈압의 ±20~49%	1
	마취-진정 전 혈압의 ±50%	0
의식상태	완전 회복 의식상태	2
	부르면 눈 뜸	1
	무반응	0
산소포화도	대기 중 산소포화도 >92% 유지	2
	산소투여로 산소포화도 >90% 유지	1
	산소투여에도 불구하고 산소포화도 <90%	0

부록 4. 위내시경설명서 및 동의서

위내시경 검사 설명서/동의서

1. 위내시경 검사란?

위내시경 검사는 내시경을 통해 식도, 위, 십이지장 점막을 직접 눈으로 관찰하여 염증, 궤양, 폴립(용종), 암 등의 질환을 진단하는 검사입니다. 상부위장관 조영술과 같은 방사선 검사와는 달리 위내시경 검사는 이상이 발견되면 조직검사를 통해 정확한 진단이 가능하고 치료 방침을 결정하는데 크게 도움이 되는 검사입니다.

2. 검사 전 주의사항

1) 검사 전날 저녁 식사는 오후 6시경 소화되기 쉬운 음식을 드시고 밤 9시부터 물 이외에는 아무것도 드시지 마십시오. 밤 12시 이후로는 물도 드시지 마십시오.
   - ❖ 술, 담배도 안됩니다. 단 혈압약은 물 반 컵 정도로 검사 당일 아침에 꼭 드십시오.
   - ❖ 아스피린과 같은 항혈소판제제나 항응고제(와파린 등)를 드시는 분은 담당 주치의에게 약 복용 여부에 대해 반드시 확인 후 복용 중지 여부 및 기간에 대해 상의 받으시기 바랍니다.
2) 당뇨병이 있는 분은 검사 당일 아침에 인슐린 주사를 맞지 마시고 당뇨약도 드시지 마십시오.
3) 간, 심장, 폐, 신장, 혈액 질환, 고혈압, 당뇨병 등 각종 병력이 있을 경우 반드시 담당 의사와 상의해야 합니다.
4) 도난, 분실의 염려가 있는 귀중품을 가지고 오지 마십시오.
5) 검사 도중 조직검사나 기타 검사를 시행한 경우에는 추가 수납이 있습니다.
6) 검사 전에는 의치를 빼주십시오.

3. 검사 과정

검사 전 가스제거제를 복용하고 국소마취제를 구강 내에 뿌려 목을 마취합니다. 혀와 목에 힘을 빼고 코와 배로 천천히 깊게 숨을 쉬면서 기침을 참고 지시에 따르면 쉽게 내시경 삽입이 가능합니다. 검사자가 내시경으로 점막을 관찰하는 동안 수검자는 천천히 심호흡 하면서 구역, 구토를 참고 입안에 고인 침을 삼키지 말고 자연스럽게 흘리면 됩니다.

4. 검사 과정 중 발생할 수 있는 합병증 및 문제점

1) 장운동 억제제를 투여받을 경우에 녹내장 및 전립선비대증 환자에게서 부작용을 일으킬 수 있으므로 사전에 의료진에게 알려주셔야 예방할 수 있습니다.
2) 내시경 삽입하는 과정에서 치아가 부러지거나 빠져서 기도로 들어갈 위험이 발생할 수 있습니다.
3) 위 내에 잔여물이 남아 있거나 환자의 협조가 어려워 더 이상 내시경 검사를 진행할 수 없는 경우에 내시경을 삽입하였더라도 검사를 중단할 수 있습니다.
4) 내시경 검사를 시행하는 동안 사용하는 약물에 의한 과민반응, 저산소증이나 폐렴 같은 호흡기 합병증, 뇌졸중, 심근 경색증 및 쇼크 같은 순환기계 합병증, 감염, 출혈, 천공, 복통 등이 발생할 수 있습니다.

내시경 검사 중 발생하는 출혈의 경우 대부분 내시경을 이용하여 지혈이 가능하나 일부 출혈의 경우 혈관 색전술 치료 또는 수술적 치료를 위해 입원이 필요한 경우도 있을 수 있습니다. 또한, 천공이 발생한 경우 내시경을 이용한 봉합술, 항생제 치료 또는 수술적 치료가 필요할 수 있습니다.
극히 드물지만, 합병증에 대한 적절한 치료에도 불구하고 치료에 반응하지 않을 경우 사망에 이를 수도 있습니다.

5. 검사 후 주의사항

1) 검사 후 목마취로 인해 이물감이 느껴지지만 한 시간 정도 지나면 대부분 가라앉습니다.
2) 물이나 음식은 목 마취가 완전히 풀린 후 (검사 1~2시간 후) 드십시오.
3) 검사 후 2~3일 정도는 목이 불편할 수 있습니다.
4) 검사 후 출혈(혈변, 검은색 변)이 발생하면 담당 진료의에게 알려주십시오.
5) 검사 당일 너무 뜨겁거나 자극적인 음식은 피하시고 특히 술과 담배는 삼가십시오.
6) 진정내시경을 받는 경우 검사 당일에는 운전하면 안 되고 환자 안전을 위해 보호자가 동반해야 합니다. 또한, 운동 및 사우나를 자제하시고, 기계를 다루거나, 중요한 결정을 내리는 일은 시행하여서는 안 됩니다.
7) 조직검사 결과는 1주일 정도 소요됩니다. 검사 결과는 외래 진료 예약일에 확인하시면 됩니다.

위내시경을 받으시겠습니까? **☐예** **☐아니오**

내시경 검사 시 이상이 발견되면 정확한 진단을 위하여 조직검사를 추가로 할 수 있습니다. 추가 비용이 발생합니다. 내시경 검사 중 조직검사를 시행하는 것에 동의하십니까?
☐예 **☐아니오**

이에 본인(또는 대리인)은 **시술의 필요성, 과정 및 합병증**에 대하여 의료진으로부터 설명을 듣고 충분히 이해하였으며, **검사 전후 주의사항, 불가항력적으로 야기될 수 있는 합병증** 또는 **환자의 특이체질로 우발적 사고가 일어날 수 있는 것**을 사전 설명으로 충분히 이해하였습니다. 이에 자신의 자유로운 의사에 따라 본인(또는 상기 피검인)이 내시경 검사와 그에 따른 처치를 받기를 원하여 귀 병원에 검사/처치를 서면으로 신청합니다.

년 월 일

주치의(설명 의사) : _____ (인)

생년월일 : _____ 환자 : _____ (인)

환자와의 관계: _____ 보호자(법정대리인) 서명 : _____ (인)

병원 소화기내시경실(☎ -)

부록 5. 대장내시경설명서 및 동의서

대장내시경 검사 설명서/동의서

1. 대장내시경 검사란?

내시경을 통하여 항문과 직장 및 대장의 내부를 관찰하는 검사로 직장 또는 대장에 발생하는 폴립(용종), 악성신생물(암), 출혈 및 장질환의 진단 및 치료에 유용한 검사법입니다. 관찰을 위해 공기를 주입하므로 검사 중, 검사 후 복부팽만감, 불쾌감이 발생할 수 있으며, 이러한 불편감을 완화하기 위하여 검사 전 미리 진통제 또는 진정약물을 투여받고 검사를 시작할 수 있습니다. 대장조영술과 같은 방사선 검사와는 달리 대장내시경 검사는 병변이 발견되면 조직검사를 시행하여 정확한 진단을 내리고 치료 방침을 결정하는데 매우 유용한 검사입니다.

2. 검사 전 주의사항

1) 대장내부가 깨끗하게 되어야 정확한 검사를 편하게 받으실 수 있습니다.
2) 검사 3일 전부터 질긴 채소류, 김 미역 등 해조류, 잡곡(현미쌀, 검은 쌀), 씨가 많은 과일(참외, 포도, 토마토, 수박 등)은 절대 드시지 마십시오.
3) 아스피린과 같은 항혈소판제제나 항응고제(와파린 등)를 드시는 분은 담당 주치의에게 약 복용 여부 대해서 반드시 확인 후 복용 중지 여부 및 기간에 대해서 상의 받으시기 바랍니다.
4) 검사 전날 저녁(5~6시)은 죽이나 미음을 드시고 금식하시고 검사가 끝날 때까지 금식입니다.
5) 당뇨가 있는 분은 검사 당일 인슐린 주사나 당뇨약은 절대 투여하지 마십시오. 고혈압 약을 드시는 분은 검사 당일 아침 고혈압 약만 드십시오.
6) 병원약국에서 장정결제를 받은 후 복용시간과 방법을 상세하게 설명을 들으십시오.
7) 도난, 분실의 염려가 있는 귀중품을 가지고 오지 마십시오.
8) 검사 도중 조직검사나 기타 검사를 시행한 경우에는 추가 수납이 있습니다.

3. 검사 과정

1) 대장내시경 검사는 항문을 통해 내시경을 삽입하여 전 대장을 관찰하는 검사로서 내시경 삽입 전 대장 운동 억제 및 복통 경감을 위한 약물을 주사하게 됩니다.
   예상 소요 시간은 15~30분으로 추정되나, 시술 및 검사 진행 상황에 따라 변경될 수 있습니다.
2) 검사 도중 자세한 관찰을 위해 자세를 변경하거나 복부를 압박할 수 있으며, 대장 내로 공기를 주입하기 때문에 복부 팽만감, 불쾌감, 간헐적인 복통 등이 발생할 수 있으나 검사 후 수 시간 이내에 자연 소실됩니다.
3) 대장 내시경 검사의 성공 가능성은 장정결 상태, 대장의 구조적 특성에 따라 달라질 수 있으나 대체로 95% 이상에서 검사를 성공적으로 완료할 수 있습니다.

4. 검사 과정 중 발생할 수 있는 합병증 및 문제점

1) 드물지만 일부 환자에서 대장의 심한 유동성, 복부 수술이나 복막염 등으로 인한 장유착으

로 전대장 관찰이 불가능한 경우가 발생할 수 있습니다.

2) 충분한 장정결이 되지 못한 경우 검사가 불가능하기 때문에 추가로 장정결제를 복용하고 검사하거나 다른 날로 검사가 연기될 수 있습니다.
3) 검사 도중 병변이 발견될 경우 필요에 따라 조직 생검을 시행하게 되며, 용종이 발견될 경우 환자 또는 보호자의 동의하에 용종절제술을 시행하거나 동의가 되지 않거나, 제거가 어려운 경우에 폴립(용종) 절제를 위한 시술 일정을 다시 예약하여 제거하는 경우도 있습니다.
4) 대장내시경 검사는 비교적 안전한 검사이지만 환자의 특이 체질 및 대장의 구조적 특이성 때문에 드물게 합병증이 발생할 수 있습니다.
5) 합병증으로는 내시경 검사를 시행하는 동안 사용하는 약물에 의한 과민반응, 출혈, 대장의 천공, 감염, 호흡장애, 뇌졸중, 심근 경색증 및 쇼크 같은 순환기계 합병증, 혈압의 급격한 변화, 복통, 용종절제응고증후군(Postpolypectomy coagulation syndrome) 및 기타 합병증(비장파열, 급성 충수염, 급성 게실염, 피하기종) 등이 발생할 수 있습니다. 합병증 중에서 장천공은 진단내시경 검사에서는 0.3~0.4%, 용종절제술을 시행하는 경우 1% 미만의 환자에서 발생할 수 있습니다. 내시경 검사 중 발생하는 출혈의 경우 대부분 내시경을 이용하여 지혈이 가능하나 일부 출혈의 경우 혈관 색전술 치료 또는 수술적 치료를 위해 입원이 필요한 경우도 있을 수 있습니다. 또한, 천공이 발생한 경우 내시경을 이용한 봉합술, 항생제 치료 또는 수술적 치료가 필요할 수 있습니다.

   합병증 발생 시 그 종류에 따라 통원 또는 입원 치료를 필요로 하게 되며, 경우에 따라 전신 마취 하에 응급 수술이 시행될 수도 있습니다. 극히 드물지만, 합병증에 대한 적절한 치료에도 불구하고 치료에 반응하지 않는 경우 사망에 이를 수도 있습니다.

5. 검사 후 주의사항

1) 검사 도중 공기주입으로 인해 검사 후에 복부 팽만과 통증이 발생할 수 있습니다. 이를 해소하기 위해 복식호흡을 하며 복부 마사지를 하여 가스를 배출하도록 합니다. 따뜻한 물주머니를 복부 위에 두는 것도 도움이 됩니다.
2) 내시경 기계의 자극으로 검사 후 항문주위에 불편감과 통증이 발생할 수 있습니다. 대처방법으로 귀가 후 좌욕을 충분히 하도록 합니다(40도의 따뜻한 물에 항문을 15~20분 가량 담그는 것). 통증이 심할 경우 진통제를 구입하여 1회 정도 먹습니다.
3) 검사 당일 운전, 기계를 다루거나, 사우나, 심한 운동은 하지 마십시오.
4) 조직검사 후 대변에 피가 조금 섞일 수 있으나 곧 멈추며, 계속 피가 나오면(붉은색 혹은 검은색 변을 지속적으로 보는 것) 병원으로 오시기 바랍니다.
5) 검사 후 복통이 지속적으로 발생할 경우에도 병원으로 연락하거나 오시기 바랍니다.

대장내시경을 받으시겠습니까? **□예** **□아니오**

내시경 검사 시 이상이 발견되면 정확한 진단을 위하여 조직검사 또는 용종절제술을 추가로 시행할 수 있으며, 추가 비용이 발생합니다. 내시경 검사 중 조직검사 또는 용종절제술을 시행하는 것에 동의하십니까?

□예 **□아니오**

이에 본인(또는 대리인)은 **시술의 필요성, 과정 및 합병증**에 대하여 의료진으로부터 설명을 듣고 충분히 이해하였으며, **검사 전후 주의사항, 불가항력적으로 야기될 수 있는 합병증** 또는 **환자의 특이체질로 우발적 사고가 일어날 수 있는 것**을 사전 설명으로 충분히 이해하였습니다. 이에 자신의 자유로운 의사에 따라 본인(또는 상기 피검인)이 내시경 검사와 그에 따른 처치를 받기를 원하여 귀 병원에 검사/처치를 서면으로 신청합니다.

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병원 소화기내시경실(☎ -)

첨부자료 1

Communication from the ASGE Quality Assurance in Endoscopy Committee

GUIDELINE

Guidelines for safety in the gastrointestinal endoscopy unit

EXECUTIVE SUMMARY

Historically, safety in the gastrointestinal (GI) endoscopy unit has focused on infection control, particularly around the reprocessing of endoscopes. Two highly publicized outbreaks in which the transmission of infectious agents were related to GI endoscopy have highlighted the need to address potential gaps along the endoscopy care continuum that could impact patient safety.

In 2009, the Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage eliminated the distinction between a sterile operating room and a non-sterile procedure room. Hence, GI endoscopy units are now held to the same standards as sterile operating rooms by CMS[1] without evidence demonstrating that safety or clinical outcomes in endoscopy are thereby improved. Although the American Society for Gastrointestinal Endoscopy (ASGE) has previously published guidelines on staffing, sedation, infection control, and endoscope reprocessing for endoscopic procedures (Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011; Infection control during GI endoscopy; Minimum staffing requirements for the performance of GI endoscopy; Multisociety sedation curriculum for gastrointestinal endoscopy),[2-5] the purpose of this document is to present recommendations for endoscopy units in implementing and prioritizing safety efforts and to provide an endoscopy-specific guideline by which to evaluate endoscopy units. As a general principle, requirements for safety ought to be rooted in evidence that demonstrates a benefit in outcomes. When data are absent, these requirements may be derived from experts with experience in the safe delivery of care in the GI endoscopy setting. Additionally, consideration should be given to the promotion of efficient care and cost containment, with avoidance of requirements unsupported by evidence that then contribute to rising healthcare costs.

Over the past 2 years, surveyors have called into question accepted practices at many accredited endoscopy units seeking reaccreditation. Many of these issues relate to the Ambulatory Surgical Center Conditions for Coverage set forth by CMS and the lack of distinction between the sterile operating room and the endoscopy setting. The following is a summary of issues that have been faced by endoscopy units throughout the country along with the ASGE position and accompanying rationale.

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ISSUES AND RATIONALE

1. Issue: Structural requirements for 40-inch doors and room sizes >400 square feet required of sterile operating rooms
   Position: Standard 36-inch doors, if they accommodate patient transport mechanisms, and room sizes 180 square feet are adequate and safe for endoscopy units because they do not use the same large equipment or number of staff as the operating room.[6]
2. Issue: Requirement for a written policy on traffic patterns in the endoscopy unit
   Position: The unit should define low-risk exposure and high-risk exposure areas and activities within the endoscopy unit and describe the attire and personal protective equipment (PPE) that should be worn in each area. Endoscopy staff can move freely throughout the unit provided that there is appropriate use and changing of PPE.
3. Issue: Requirement for endoscopy personnel to don full sterile operating room PPE, including new scrubs, hair covers, and booties
   Position: It is recommended that staff directly engaged in GI endoscopy or in processes in which splash or contamination could occur wear gloves, face and/or eye shields, and impervious gowns. Units should develop policies that are consistent with Occupational Safety and Health Administration and state-mandated recommendations for wearing face and/or eye shields or masks.[7] Scrubs or other attire may be worn from home because endoscopy is not a sterile procedure.

Likewise, there is no need for hair covers or booties. Staff must remove and appropriately discard used PPE before leaving the procedure area.

4. Issue: Supervision of moderate sedation
   Position: Moderate sedation may be administered safely under the supervision of a non-anesthesia physician who is credentialed and privileged to do so.
5. Issue: Role of capnography
   Position: There is inadequate data to support the routine use of capnography when moderate sedation is the target.
6. Issue: Requirement that 2 nurses (1 monitoring, 1 circulating) are present when moderate sedation is performed
   Position: When moderate sedation is the target, a nurse should monitor the patient and can perform interruptible tasks. If more technical assistance is required, a second assistant (nurse, licensed practical nurse [LPN], or unlicensed assistive personnel [UAP]) should be available to join the care team.
7. Issue: Staffing requirements when sedation and monitoring is provided by anesthesia personnel
   Position: When sedation and monitoring are provided by anesthesia personnel, a single additional staff person (nurse, LPN, or UAP) is sufficient to assist with the technical aspects of the procedure.
8. Issue: Technical capabilities of technicians
   Position: Unlicensed technicians who have received initial orientation and ongoing training and are deemed competent by their units, can assist with and participate in tissue acquisition during the endoscopic procedure, including but not limited to the opening and closing of forceps, snares, and other accessories.

BACKGROUND

The overall risk of transmission of healthcare-associated infections during the performance of endoscopic procedures is estimated to be very low.[8] Historically, according to the Centers for Disease Control and Prevention, most cases have occurred from a breach in proper cleaning and disinfection of endoscopic equipment. Despite the low risk of healthcare-associated infections from endoscopic procedures, outbreaks of certain hospital-based healthcare-associated infections, such as *Clostridium difficile* and methicillin-resistant *Staphylococcus aureus*, have brought healthcare-associated infections to the attention of hospital administrators and other stakeholders and have raised the public's concern over safety in hospitals. In addition, several highly publicized cases of hepatitis C infection in the outpatient endoscopy setting have heightened interest in ensuring safety in ambulatory endoscopy centers and office-based endoscopy units. The outbreak of hepatitis C among patients undergoing endoscopy at 2 facilities owned by a single physician in Nevada was attributed to improper injection techniques, whereas an infection control breach among patients who underwent colonoscopy at 2 U.S. Department of Veterans Affairs medical centers in Florida and Tennessee was attributed to installation of an improper irrigation valve on the endoscope and failure to change irrigation tubing between cases.[9,10] Although the risk of infections from endoscopic procedures, regardless of the setting, remains low, these cases highlight the need to address potential gaps along the endoscopy care continuum that may impact patient safety outcomes.[2-5]

Changes to the CMS Ambulatory Surgical Center Conditions for Coverage that went into effect in 2009 eliminated the distinction between a sterile surgical room and a non-sterile procedure room, providing further impetus for this guideline. As a result of these conditions, non-sterile procedure environments, including endoscopy units, are now held to the same standards as sterile operating rooms even though requirements for facilities, infection control, staffing, and sedation applicable to the sterile operating room may not be relevant or necessary for endoscopy units. To date, the Association of periOperative Registered Nurses and other organizations have set standards for sterile operating environments.[11] This document is endorsed by organizations with specific expertise in the safe delivery of care in the non-sterile, GI endoscopy environment, which recognize the important distinction between the endoscopy and sterile operating room settings. Safety in the GI endoscopy unit begins with clear and effective leadership that fosters a culture of safety including team work, openness in communication, and efforts to minimize adverse events. Although issues of governance and culture are important, they are outside the scope of this document. Table 1 provides a summary of the key strategies to maintain safety in the GI endoscopy unit.

FACILITIES

Facilities are the foundation of a unit, the layout of which should provide a safe environment for patients and staff. Facilities should be designed to comply with local and state building codes as well as the National Fire Protection Association (NFPA) 101 Life Safety Code.[12] The specific version of the Code will depend on currently accepted practice for CMS and state regulations.[13,14] Recommendations for facility standards are largely based on expert opinion and put into practice by accreditation bodies; however, no association with patient outcomes has been shown.

Recommendations for architectural layout

Each unit should have a designated flow for the safe physical movement of dirty endoscopes that does not cross-contaminate clean endoscopes coming out of the cleaning process and their storage. Although circular flow

TABLE 1. Summary of the key strategies to maintain safety in the GI endoscopy unit

Each unit should have a designated flow for the safe physical movement of dirty endoscopes and other equipment.
Procedure rooms vary in size, with more complex procedures requiring greater space for more specialized equipment and, in some cases, additional staff.
Before starting an endoscopic procedure, the patient, staff, and performing physician should verify the correct patient and procedure to be performed.
A specific infection prevention plan must be implemented and directed by a qualified person.
Gloves and an impervious gown should be worn by staff engaged in direct patient care during the procedure.
The unit should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day.
For patients undergoing routine endoscopy under moderate sedation, a single nurse is required in the room in addition to the performing physician.
Complex procedures may require additional staff for efficiency but not necessarily for safety.
At a minimum, patient monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery, and before discharge.
For cases in which moderate sedation is the target, the individual responsible for patient monitoring may perform brief interruptible tasks.
For cases in which moderate sedation is the target, there is currently inadequate data to support the routine use of capnography.

is preferable, some units may be constrained by the existing footprint of the facility.

Recommendations for the endoscopic procedure room. Endoscopic procedure rooms vary in size, with more complex procedures such as ERCP requiring greater space for more specialized equipment and possibly additional staff. For endoscopy, procedure rooms should not be held to the same standards as sterile operating rooms, which require space for anesthesia support and a greater number of staff members and bulkier equipment, none of which are essential for the performance of endoscopy. Standard endoscopic procedures require less space, with requirements varying from as little as 180 square feet to 300 square feet.[6]

The following are issues within the endoscopic procedure room that are related to patient safety:

1. Actual marking of the site is not required for endoscopic procedures because endoscopy does not involve lateral right-left distinction levels such as those found in spinal procedures or those done on multiple structures such as fingers or toes. Before starting an endoscopic procedure, the patient, staff, and performing physician should verify the correct patient and procedure to be performed.
2. A reliable and adequate source for oxygen is required. Sources may include in-wall or free-standing oxygen. In some units, carbon dioxide may be used for insufflation of the GI lumen, but this is not a requirement.
3. A suction source for the equipment and patient must be present either in-wall or portable. For tubing and portable suction, the manufacturer's guidelines must be followed.
4. An uninterruptible source of power, supplied either by a generator or battery source is required. The purpose of a secondary power source is to allow completion of the current procedure in the event that the primary power source malfunctions. Procedures should not be started when the only source of power is the secondary source.
5. Units must practice fire safety in adherence with the NFPA 101 Life Safety Code, which also dictates the number and type of electrical outlets tied to the generator.[12] The NFPA 101 Life Safety Code recommends that not all outlets be tied to the generator in case the generator fails to disengage once power is restored.
6. The unit's defibrillator and crash cart should be checked at the beginning of each day to ensure that all components are functional, fully stocked, and readily accessible.
7. The routine monitoring of temperature and humidity within the endoscopic procedure area, although advocated by CMS to theoretically curtail growth of microorganisms and reduce fire hazard, has not been associated with safety outcomes in endoscopic units. In the absence of published guidelines on the optimal ranges for these parameters, routine monitoring of temperature and humidity is not currently warranted.[1]
8. Puncture-resistant containers for biohazardous materials and sharps should be located so that sharps are not passed over the patient.[15]
9. If special therapeutic procedures are planned, specific room features may be required, such as leaded walls when flat-table fluoroscopy is utilized.[16]

Recommendations for the endoscopic recovery area

1. The recovery bays should provide privacy and sufficient space for monitoring and care. The minimum space per bay has not been established. Unit facilities must be able to provide the level of recovery appropriate to the level of sedation utilized.[17]

Recommendation for storage of supplies

1. Sterile supply items such as intravenous (IV) solutions should be protected from splash contamination during environmental cleaning (8-10 inches off the floor), damage from compression (stacking only ridged containers), and water damage (no storage under sinks).
2. Units should have a process for periodically verifying that supplies marked with an expiration date have not expired. Compliance with this process should be documented.

INFECTION CONTROL

ASGE has published several guidelines detailing ways to minimize the risk of transmission of infection within the endoscopy unit.[2,18] In addition to meticulous endoscope reprocessing, a specific infection prevention plan must be implemented to prevent the transmission of pathogens in the unit and to provide guidance should a breach occur. Active Infection Prevention Surveillance programs and ongoing educational and competency evaluation of staff regarding activities within the preprocedure, intraprocedure, and postprocedure phases are necessary to ensure overall safety of patients and healthcare workers. Infection prevention plans for a specific unit must be directed by a qualified person. Although state regulations may vary, CMS allows the unit to designate the specific training and competency of the individual.

The infection prevention plan must be documented in writing and should include a set of policies and procedures appropriate for and targeted to the specific procedures performed in addition to likely sources of nosocomial infection in the unit. The plan should include a process for the ongoing assessment of compliance with the program and methods for correction.

Standard precautions, the minimum infection prevention practices applicable to all patient care regardless of the suspected or confirmed infection status of the patient, are the foundation of a sound infection prevention strategy. These include:

1. Hand hygiene
2. PPE
3. Safe medication administration practices
4. Safe handling of potentially contaminated equipment or surfaces in the patient environment.[19]

Recommendations for hand hygiene

Proper hand washing is considered to be the cornerstone of preventing the transmission of pathogens.

1. Hand hygiene should be performed before patient contact (even if gloves are to be worn); after patient contact and before exiting the patient care area; after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn); before performing invasive procedures (ie, placement or access of intravascular lines); and after glove removal.[20]
2. The use of soap and water is required when hands are visibly soiled and after caring for patients with known or suspected infectious causes of diarrhea such as *C difficile*. Otherwise, the use of alcohol-based hand agents is adequate.[21]

Recommendations for PPE

The unit should have written policies and procedures regarding PPE that defines activities in which PPE should be worn and the appropriate type.[22] For sterile environments, the use of PPE is commonly dictated by the traffic pattern and location of care, defined as unrestricted, semi-restricted, and restricted areas.[23] In contrast, in the non-sterile endoscopy environment, the use of PPE is dependent on the degree to which staff have the potential to come into direct contact with patients and their bodily fluids during specific activities, rather than the location of care. The risk of exposure can be categorized into low-risk exposure and high-risk exposure, which are defined as follows:

1. Low-risk exposure: Any personnel not in direct contact with a contaminated endoscope, device or bodily fluid or with the potential for splash contamination. For example, personnel entering the procedure area for a brief period of time who are not involved in direct patient care are considered at low-risk exposure.
2. High-risk exposure: Any personnel working in direct contact with a contaminated endoscope, device, or bodily fluid or any personnel in direct patient care with the potential to come into contact with a contaminated endoscope, device, or bodily fluid.

Low-risk exposure activities require no PPE. Personnel whose exposure status may change during an endoscopy procedure should have immediate access to PPE should the need arise. High-risk exposure activities require the use of gloves and impervious gowns. Because of the potential for splash exposure to the face, individual units should develop policies based on Occupational Safety and Health Administration and state-mandated recommendations for wearing face and/or eye shields or masks.[22] Hair and shoe covers and gown classifications above Association for the Advancement of Medical Instrumentation level 1 are often included in PPE recommendations.[24] These items generally are mandated for the sterile operating room environment, but there is no evidence to

support their requirement or benefit in the non-sterile endoscopy environment.

1. Staff must remove and appropriately discard used PPE before leaving the procedure room. PPE should not be reused or worn to care for more than 1 patient.
2. Scrub attire may be worn from home, because endoscopic procedures are performed in a non-sterile environment.
3. Individuals may elect to wear regular clothing covered by an impervious gown. There is no requirement to change clothing once the individual arrives at work.
4. If clothing under the procedure room attire is contaminated with a significant amount of blood or body fluids, the items should be placed in a bag, identified as a potential biohazard, then sent for cleaning to a laundry facility capable of properly cleaning and disinfecting clothing used in healthcare settings.

Recommendations for safe medication administration practices

Safe medication administration practices promote safety in medication administration and have become a highly scrutinized activity within healthcare,[25] in part because of evidence of pathogen transmission resulting from the improper use or reuse of syringes, multiple-dose drug vials, and IV equipment. The Centers for Disease Control and Prevention and ASGE have issued guidelines outlining safe injection practices.[3,19,26] Units should adhere to the following:

1. Preparing medications for multiple patients should be done in an area away from direct patient care or procedure rooms.
2. Units should appropriately label all medications, including those used for sedation, unless the medication is for immediate use (prepared and administered immediately without leaving the provider's hand).[26]
3. Medications marked either on the container or noted in the package insert as "single patient use" should be used for a single patient only and any remaining drug should be discarded.
4. Units should use new fluid administration sets (eg, IV tubing) for each patient.
5. Units should prepare and administer injections by using aseptic technique (ie, cleansing the access diaphragms of medication vials with 70% alcohol before inserting a device in the vial). Single-dose vials, ampules, bags, or bottles of IV solution should be used for a single patient only.
6. Use of a single-dose vial is preferred over multiple-dose vials, particularly when medications will be administered to multiple patients.[3]
7. If a multiple-dose vial will be used for more than 1 patient, they should remain in a centralized medication area and should not enter the patient procedure area. These should be dated when opened and discarded according to protocols, in compliance with nationally accepted guidelines, such as those published by the Centers for Disease Control and Prevention.[27]
8. Units should not re-use a syringe to enter a medication vial or solution, even with a new needle.
9. Units should not use the same syringe to administer medications to multiple patients regardless of whether the needle is changed or an intervening length of IV tubing is used.
10. Units should dispose of used syringes and needles at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof.[28]
11. Units should develop a clearly defined policy for the management of sharps and sharps-related injuries, including the reporting of blood and body fluid exposures. This should be in compliance with federal, state, and local guidelines.
12. Units should maintain a log of sedation medications wasted between patients that can be used to reconcile used and wasted vials at the end of the day.
13. If tubes of lubricant are used for more than one examination, the unit should observe appropriate infection control habits and discard any tube that has potentially been contaminated.
14. Although the multiple-society guideline recommends using sterile water in the irrigation bottle, it is acceptable to use tap water because this has been shown to be safe.[29] The rates of bacterial cultures are no different with the use of tap water versus sterile water, and neither has been associated with clinical infections.[30,31]
15. Units should follow federal and state requirements for the protection of healthcare personnel from exposure to blood-borne pathogens.

Recommendations for safe handling of potentially contaminated equipment or surfaces

Environmental cleaning of surfaces with an appropriate Environmental Protection Agency–labeled disinfectant is mandatory, especially for surfaces that are most likely to become contaminated with pathogens, such as those in close proximity to the patient (eg, side rails) and other frequently touched surfaces in the unit. Facility policies and procedures should address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious material.[20,32] Units should:

1. Maintain material safety data sheets for all chemicals used for cleaning and disinfection. These sheets should detail the safe and proper use and emergency protocol for a chemical. Material safety data sheets should be used for training staff on each chemical's safe use.
2. Follow the manufacturer's directions for surface disinfection of patient care items.

- Appropriate contact time of disinfectant to achieve germicidal kill should be followed.
- Alcohol should not be used to clean environmental surfaces.

3. Properly clean and disinfect surfaces that are frequently touched by personnel or dirty equipment in the endoscopic procedure area at the beginning of the day, between cases, and during terminal cleansing. Frequently-touched surfaces may include endoscopy keyboards and video monitors and consoles.

Recommendations for terminal cleansing

Terminal cleansing involves the cleaning of surfaces to physically remove soil and biofilm, followed by proper disinfection. Typically, this requires use of 2 distinct agents because chemical disinfectants are not effective at cleansing, and cleansing agents are not effective at disinfecting surfaces.

1. The unit should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day.
2. Agents for terminal cleansing should have efficacy in spore removal, which may differ from requirements for agents used in sterile operating rooms.
3. Before the first case of the day, staff should verify that all procedural and recovery areas have been properly cleansed.
4. A training and competency assessment program should be in place for staff members who are involved in terminal cleansing to ensure proper and safe handling and use of the chemicals.

Recommendations for reusable medical equipment

The reprocessing protocol of reusable medical equipment such as endoscopes and endoscopic accessories must be strictly followed.[3] The details of reprocessing according to their Spaulding Classification are well described.[33] These policies should be a part of the unit's policies and procedures and core competency assessment.

Single-use devices as determined by the manufacturer label or packaging insert may not be reprocessed unless they are specifically listed in the U.S. Food and Drug Administration (FDA) 510(k) database. If so, they must be reprocessed by entities that have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific single-use devices.[34]

Written policies and procedures regarding infection control for a unit should be documented.

STAFFING

Staffing requirements for the performance of GI endoscopy should be based on what is required to create a safe environment for the patient and to ensure the safe performance of the endoscopic procedure. The minimum safe staffing of an endoscopy room is outlined in the ASGE *Minimum staffing requirements for the performance of GI endoscopy.*[4] For patients undergoing routine endoscopy under moderate sedation, a single registered nurse (RN) is required. There is no evidence that staffing beyond a single RN improves the safety of the patient. There are some circumstances in which additional assistance can be helpful for the technical aspects of the procedure, such as in ERCP, yet there are no published safety or clinical outcomes data to support the routine use of a circulating nurse for endoscopic procedures. Guidelines for staffing requirements in other settings, such as the sterile operating room, do not apply to the endoscopic procedure room because of inherent differences in these settings.[35]

Both patient and procedural factors should be considered in determining staffing requirements. Patient factors that affect staffing requirements include the level of sedation that is planned (ie, whether the patient is receiving no sedation, moderate sedation, or deep sedation) and the medical condition of the patient, which is determined from the history and physical examination and is reflected in the American Society of Anesthesiologists (ASA) Physical Status Classification System score of the patient. Procedural factors include the anticipated length of the procedure and whether the procedure is intended to be diagnostic or whether a therapeutic intervention is planned. Complex interventional procedures, such as EUS and ERCP may require additional staff for efficiency, but there is no evidence to suggest that this improves safety or patient outcomes.

Recommendations for preprocedure staffing

1. Staffing models in the preprocedure area should support activities required to prepare patients for endoscopy.
2. The ratio of RNs to patients in preprocedure care is variable depending on the complexity of the patient mix.

Recommendations for intraprocedure staffing based on level of sedation[4]

1. No sedation—One assistant (RN, LPN, or UAP) other than the physician performing the procedure should be present to assist with the technical aspects of the procedure.
2. Moderate sedation (also known as conscious sedation)—Sedation should be directed by a physician who is credentialed and privileged to do so. Moderate sedation can be administered by an RN. During the period in which the patient is sedated, the RN must monitor the patient for vital sign changes, hypoxemia, and comfort. The RN may assist with minor, interruptible tasks. In the event that more intense technical assistance is

required, a second assistant (RN, LPN, or UAP) should be available to join the care team for the technical aspects of the procedure.

3. Deep sedation—Most institutions require that deep sedation be administered by an anesthesia professional such as an anesthesiologist, certified registered nurse anesthetist (CRNA), or anesthesiologist assistant who is credentialed and privileged to do so. In this situation, the anesthesia provider should be responsible for administering sedation and monitoring the patient. A second staff person (RN, LPN, or UAP) is required to assist with technical aspects of the procedure.[4,17]

Recommendations for postprocedure staffing

1. An RN is required to monitor patients who have received sedation until the patient is stabilized and to assess for adverse events related to the endoscopic procedure.
2. Once the patient is stable, postprocedure activities such as providing food or drinks and assistance in changing clothes can be performed by an RN, LPN, or UAP.
3. The ratio of RNs to patients in the postprocedure setting is variable depending on the complexity of the patient mix.

Recommendations for training

1. Sedation—Sedation should be administered by an RN under the supervision of the endoscopist who is credentialed and privileged to do so or by anesthesia personnel (physician or CRNA) who are credentialed and privileged to do so. These individuals should be specifically trained in endoscopic sedation, including the modes of action and adverse events of the sedative agents being used. This training should be documented. The staff administering sedation must have the knowledge and skills to recognize when the sedation level becomes deeper than planned and to manage and support patients' cardiopulmonary responses to sedation accordingly. On verification of the RN's training, the unit should document the privileging of the RN to provide moderate sedation under the direct supervision of a physician. LPNs and UAPs are not qualified to administer sedation.
2. Technical assistance—Technical assistance can be provided by a variety of staff members, including UAPs, LPNs, RNs, and GI technicians. Training in the use of endoscopic equipment, accessories, and ancillary equipment should be documented and include an objective assessment of initial competence and annual competency testing thereafter to ensure and document that skills are maintained.
3. Basic and advanced cardiac life support—All staff with clinical responsibilities must have basic life support certification. At least one individual with advanced cardiac life support certification must be present in the unit when patients are present.
4. A written policy on staff training along with the type and frequency of core competency assessment should be documented.

ENDOSCOPIC SEDATION

Sedation can improve the quality of GI endoscopy, the likelihood of a thorough and complete examination, patient satisfaction, and patient willingness to undergo examination or reexamination. The choice of specific sedation agents and the level of sedation targeted should be determined on a case-by-case basis by the endoscopist in consultation with the patient. Endoscopy without sedation may be appropriate in some instances. For a detailed discussion including supporting evidence, please refer to the 2008 ASGE guideline: *Sedation and Anesthesia in GI Endoscopy*.[17]

Recommendations for the sedation-related environment

1. Units should comply with applicable federal and state laws regarding licensure and/or certification of all staff involved in the administration and monitoring of sedation and document training and competencies.
2. Established discharge criteria should be attained before discharge from the endoscopy unit. Patients who received IV sedation during their endoscopic procedure should be discharged in the presence of a responsible individual. A written policy on discharge requirements should be documented.
3. An agreement should exist between the unit and a hospital facility for the transfer of patients who require escalation of care. A written transfer agreement should be documented.
4. A focused history and physical examination, including the patient's current medications and ASA classification, should be completed before the start of the procedure.[17]

Recommendations for sedation-related equipment

1. All sedation-related equipment, before initial use and then at intervals dictated by the manufacturer's guidelines, should be examined and verified to be in proper working order by a qualified biotechnician.[36]
2. Oxygen, suction for the mouth, and electronic equipment that can monitor and display pulse, blood pressure, oxygen saturation, and continuous electrocardiographic rhythm assessment should be available in the procedure room. A written policy for equipment checks and maintenance should be in place. A log to monitor compliance should be maintained.

Recommendations for patient monitoring

1. All patients undergoing endoscopy should be monitored, the frequency of which depends on procedural and patient factors (eg, type of sedation, duration and complexity of procedure, patient condition). At a minimum, monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery, and just before discharge.[5]
2. Units should have procedures in place to rescue patients who are sedated deeper than intended.[5,17,37,38]
3. When the target level is moderate sedation (also known as conscious sedation):
   - The individual assigned responsibility for patient monitoring may perform brief, interruptible tasks.[4,5]
   - Minimal monitoring requirements include electronic assessment of blood pressure, respiratory rate, heart rate, and pulse oximetry combined with visual monitoring of the patient's level of consciousness and discomfort.
   - Currently, there are inadequate data to support the routine or required use of capnography during endoscopic procedures in adults when moderate sedation is the target.[5,39,40]
4. When deep sedation is targeted:
   - The individual responsible for patient monitoring must be dedicated solely to that task and may not perform any other function during the procedure.[4,5]
   - The use of capnography in EUS, ERCP, and colonoscopy to assess the adequacy of ventilation may reduce the incidence of hypoxemia and apnea,[41,42] but its impact on the frequency of other sedation-related adverse events such as bradycardia and hypotension is unknown. As such, capnography may be considered for the performance of endoscopy under deep sedation. However, there is no safety data to date to support the universal use of capnography in such cases.
   - Documentation of the clinical assessments and monitoring data during sedation and recovery is required.

Recommendations for medications

1. Written policies detailing the methods of drug storage, monitoring of drug inventory and expiration dates, and documentation of compliance with these policies are required.
2. There should be an individual qualified by training and licensure (such as a physician or pharmacist) who is directly responsible for overseeing medication usage in the unit.
3. Medications should be securely stored under environmental conditions consistent with the manufacturer's instructions on the label. The use of single-dose vials for all sedative and analgesic medications is strongly recommended.
4. Controlled substances should be stored in a double-locked cabinet, and a daily medication log compliant with state and federal regulations should be maintained. Disposal of unused narcotics and other controlled drugs should be witnessed by 2 individuals and documented.
5. Medications should be given only under the order of the supervising physician or anesthesia professionals when applicable.
6. Reversal agents for opioids and benzodiazepines should be readily available.
7. A written policy should be in place for the identification, documentation, and review of adverse drug reactions.

Recommendations for emergency management

1. Appropriate pharmaceutical agents, oxygen, oral suction, laryngoscope, Ambu bag, and defibrillator should be readily available in the unit.
2. Units should train and periodically provide in-service education for staff in the use of equipment for emergency management.[4] Training and assessment of competency should be documented.

DISCLOSURES

All authors disclosed no financial relationships relevant to this article.

Abbreviations: ASA, American Society of Anesthesiologists; ASGE, American Society for Gastrointestinal Endoscopy; CMS, Centers for Medicare and Medicaid Services; CRNA, certified registered nurse anesthetist; FDA, U.S. Food and Drug Administration; GI, gastrointestinal; IV, intravenous; LPN, licensed practical nurse; NFPA, National Fire Protection Association; PPE, personal protective equipment; RN, registered nurse; UAP, unlicensed assistive personnel.

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Society of Gastroenterology Nurses and Associates, Inc.

GUIDELINE

Quality indicators for gastrointestinal endoscopy units

Prepared by: ASGE ENDOSCOPY UNIT QUALITY INDICATOR TASKFORCE

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INTRODUCTION

Significant efforts have been dedicated to defining what constitutes high-quality endoscopy. These efforts, centered on developing, refining, and implementing procedure-associated quality indicators[1-5] have been helpful in promoting best practices among endoscopists and providing evidence-based care for our patients. At the same time, the American Society for Gastrointestinal Endoscopy (ASGE) has generated programming to assist physicians and allied healthcare professionals in understanding how to translate quality concepts into practice. With this work, we now have a stronger sense of how to measure quality at the patient and procedural level.

A critical component of high-quality endoscopy services relates to the site of the procedure: the endoscopy unit. Unlike many procedure-associated quality indicators, evidenced-based indicators used to measure the quality of endoscopy units are lacking. Outside of the United States, the United Kingdom's National Health Services developed the Global Rating Scale (GRS) in 2004[6] with the dual aims of enhancing quality while developing uniformity in endoscopy unit processes and operations. This scoring system was the first to assess service at the level of the endoscopy unit and has been instrumental in reducing wait times, identifying service gaps, increasing patient satisfaction, and reducing adverse events within endoscopy units in the United Kingdom.[7] Additionally, the GRS has demonstrated that measuring an endoscopy unit parameter repeatedly and incorporating it into a quality improvement program leads to improvement for many indicators.[6-8] Use of the GRS has spread with modification and adoption for use in other countries across Europe[8,9] and Canada.[10,11] However, there are limitations with the GRS. Whether improvements in 1 particular indicator are correlated with other areas of endoscopy unit performance and outcomes cannot be ascertained from the GRS data. Also, the process for developing and reaching consensus on the GRS indicators has varied extensively in their rigor and breadth of stakeholder participation. To date, no such effort to identify and promote endoscopy unit–level quality indicators has been performed in the United States.

A compendium of quality indicators for endoscopy units in the United States is needed to strengthen programming around the promotion of quality and to give endoscopy units an organizational framework within which they can direct their efforts. As healthcare reimbursement in the United States becomes more dependent upon demonstration of performance and quality, endoscopists, governing organizations, payers, and patients will be looking for guidance on endoscopy unit–wide performance. Consequently, the ASGE convened a taskforce whose primary objectives were to (1) develop a comprehensive document that identifies key quality indicators for endoscopy units as defined by the literature and expert opinion and (2) achieve consensus on these quality indicators from important stakeholders involved in endoscopy unit operations and quality improvement (Video 1, available online at www.VideoGIE.org).

METHODS

Endoscopy unit quality indicator taskforce

A taskforce composed of a diverse group of 16 representatives from various GI practice settings both in the United States and internationally was assembled on May 19, 2013. The taskforce consisted of gastroenterologists (14) and GI nurses (2); 8 of the members also held leadership roles within their endoscopy units. The taskforce was further divided into 5 working subgroups to address the following domains: (1) patient experience, (2) employee experience, (3) efficiency and operations, (4) procedure-related

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endoscopy unit issues, and (5) safety and infection control. The leader of each working subgroup plus the 2 taskforce chairs (L.W.D and J.C.) formed the steering committee.

Study design

The project was divided into 3 phases: (1) systematic literature review and generation of potential endoscopy unit quality indicators by each of the 5 subgroups; (2) approval of these potential endoscopy unit quality indicators by the steering committee and then rating of these potential indicators on several parameters by invited participants using a modified Delphi method; and (3) reaching consensus on a final set of endoscopy unit quality indicators. The steering committee unanimously agreed upon the methodology as outlined above.

Generation, development, and finalization of potential endoscopy unit quality indicators

Over the course of 9 months each subgroup leader conducted a systematic literature review using PubMed, Google Scholar, Embase, and Medline using key search terms to identify endoscopy unit quality indicators for their respective domain. In the absence of data that linked endoscopy unit level indicators with improved patient outcomes, subgroups relied on expert opinion and existing regulatory standards. The subgroups initially examined the work of the United Kingdom's GRS[6] and the Canadian Association of Gastroenterology consensus guidelines on safety and quality indicators[10] to help develop a framework for generating potential endoscopy unit quality indicators. The subgroups used this framework to generate a candidate list of endoscopy unit quality indicators that were then reviewed by the steering committee. The steering committee subsequently met on March 7 to 8, 2014, to refine these potential endoscopy unit quality indicators and unanimously agreed upon 155 potential quality indicators (patient experience, 46; employee experience, 33; efficiency and operations, 25; procedure-related, 24; and safety and infection control, 27) for the voting phase of the study.

For the purposes of this guideline, the taskforce defined a quality indicator as a particular parameter that is being used for comparison. A quality indicator is often reported as a ratio between the incidence of correct performance and the opportunity for optimal performance, or as the proportion of interventions that achieve a predefined goal.[12]

Reaching consensus on endoscopy unit quality indicators

Given the lack of available data on endoscopy unit quality indicators, the steering committee used a modified Delphi method[13-15] to reach consensus on which of the 155 proposed indicators to include in the final guideline. The goal of the Delphi process was to measure 2 main parameters for consensus: (1) the extent to which respondents agreed with the importance and relevance of a potential quality indicator and (2) the extent to which respondents agreed with one another.[16] The consensus process consisted of 2 rounds of online voting using the REDCap program (UCSF, San Francisco, Calif). Each participant was randomly assigned to complete a survey related to 1 of the 5 domains. There were 495 individuals invited to participate in the survey, including physicians, nurses, practice managers, and quality officers who were involved with or impacted by quality in U.S. endoscopy units.

In the first round of voting, participants provided demographic information, including gender, role within an endoscopy unit, and practice setting, and then were asked to rate each potential quality indicator on the following 4 questions:

- "Is this potential indicator an important parameter related to the quality of care for a patient in an endoscopy unit?" (ie, related to quality)
- "Is this a meaningful element of a high-quality endoscopy unit / important outcome?" (ie, meaningful to measure)
- "Is this feasible to measure?" (ie, feasible to measure)
- "Is your endoscopy unit currently compliant with this parameter?" (ie, compliance with the indicator in their own endoscopy unit)

Ratings were based on a 5-point scale (1=strongly disagree, 2=disagree, 3=neutral/uncertain, 4=agree, 5=strongly agree). Only those respondents who participated in the first round of voting were invited to participate in the second round. In the second round, participants were shown the same set of potential quality indicators along with the individual's previous response and the most common response of the overall group for the question on relatedness of the indicator to quality. Participants were then asked "How would you now rate this parameter?" using the same rating scale. Two reminder emails were sent to all invited participants during the course of the survey. No incentives were offered.

After both rounds of voting were complete, research questions were generated by each subgroup and then reviewed and unanimously agreed on by the steering committee.

Invited participants

Given that a number of groups are involved with quality as it pertains to an endoscopy unit, a broad range of individuals were invited to participate in the survey. Invited participants included the nurse manager and medical director from endoscopy units participating in the ASGE's Endoscopy Unit Recognition Program, all members of the ASGE's Quality Assurance in Endoscopy Committee, regional presidents of the Society for Gastrointestinal Nursing Association, and members of the American Gastroenterological Association and American College of Gastroenterology's committees on quality. All respondents were

TABLE 1. Characteristics of the respondents for the endoscopy unit quality indicator survey

	Patient experience, n (%)	Employee experience, n (%)	Efficiency and operations, n (%)	Procedure-related, n (%)	Safety and infection control,* n (%)	Total, N (%)
Invited, n	107	90	93	102	103	495
Any partial or complete response, n (%)	35 (32.7)	39 (43.3)	36 (38.7)	32 (31.4)	29 (28.2)	171 (34.5)
Completed part 1 only, n (%)	12 (11.2)	8 (8.9)	10 (10.8)	8 (7.8)	11 (10.7)	49 (9.9)
Completed part 1 and 2, n (%)	15 (14.0)	30 (33.3)	25 (26.9)	22 (21.6)	18 (17.5)	110 (22.2)
Female gender, n (%)	24 (68.6)	26 (66.7)	21 (58.3)	15 (46.9)	14 (50.0)	100 (58.8)
Role, n (%)						
Physician	15 (42.9)	17 (43.6)	16 (44.4)	18 (56.3)	15 (53.6)	81 (47.6)
Nurse	9 (25.7)	11 (28.2)	7 (19.4)	5 (15.6)	5 (17.9)	37 (21.8)
Practice manager	5 (14.3)	5 (12.8)	6 (16.7)	4 (12.5)	3 (10.7)	23 (13.5)
Quality officer/administrator	3 (8.6)	4 (10.3)	5 (13.9)	4 (12.5)	5 (17.9)	21 (12.4)
Other	3 (8.6)	2 (5.1)	2 (5.6)	1 (3.1)	0 (0.0)	8 (4.7)
Setting, n (%)						
Hospital-based	17 (48.6)	19 (48.7)	18 (50.0)	18 (56.3)	18 (64.3)	90 (52.9)
Ambulatory center	15 (42.9)	16 (41.0)	18 (50.0)	13 (40.6)	9 (32.1)	71 (41.8)
Office suite	3 (8.6)	3 (7.7)	0 (0.0)	0 (0.0)	1 (3.6)	7 (4.1)
VA	0 (0.0)	1 (2.6)	0 (0.0)	1 (3.1)	0 (0.0)	2 (1.2)

VA, Veterans Administration.
*Note: 1 respondent did not complete the demographics section.

deidentified with respect to name and institution during the 2 rounds of voting.

Statistical analysis

Respondent characteristics that were collected as continuous data were presented as means with standard deviations, whereas categoric data were presented as proportions (Table 1). The median was reported along with the associated percentage of individuals who reported that median for each of the questions asked on the first and second rounds of voting for all of the potential endoscopy unit quality indicators (Tables 2-6).

Potential indicators had to meet 2 initial requirements to be considered for inclusion in the final guideline (ie, the consensus threshold): (1) the indicator had to have a median of "5" (strongly agree) on the second round of voting, and (2) the indicator needed to have ≥80% of respondents rate that indicator as a "5" on the second round of voting. Afterward, only the 6 highest-rated indicators (ie, those indicators with the highest percentage scores for respondents rating that indicator a "5" in the second round of voting) from each domain were included in the final guideline. These cutoff criteria were established to identify those indicators that were rated most important by respondents and to provide endoscopy units a feasible framework for which to identify and start measuring quality indicators. Finally, from among this group of indicators, the steering committee identified 5 priority indicators that were determined as those most compelling to measure for a high-quality endoscopy unit. These 5 indicators were selected using previous definitions of a "high-priority quality indicator" and were based on clinical relevance and importance, and evidence or consensus that there was significant performance variation of the indicator among endoscopy units.[4]

To avoid excluding other important endoscopy unit quality indicators, all potential endoscopy unit quality indicators, and their representative scores from the survey, are included in Tables 2 to 6.

Ethical considerations

This study was part of an ongoing quality improvement project aimed at developing quality indicators for endoscopy units in the United States. Given that the study was related to quality improvement and no personal health information was collected at any time, formal institutional review was not required.

RESULTS

Survey respondent characteristics

There were 495 individuals that were invited to participate in the survey. The overall survey response rate for both the first and the second round of voting was 22.2% (range, 14.0% to 33.3%) with the greatest response rate in the domains of employee experience and efficiency and operations. The majority of respondents were female (58.8%) with respondent's role in the endoscopy unit being either a physician (47.6%) or a nurse (21.8%). Most

TABLE 2. Survey results using the Delphi method to examine potential endoscopy unit quality indicators for the Patient Experience domain

	1st round voting (n = 27), median (%), 1 = strongly disagree, 5 = strongly agree				2nd round voting (n = 15), median (%)
Patients' communication needs and performance	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Communication needs are recorded as part of the nursing assessment.	5	5 (64.7)	4.5 (50.0)	4 (22.9)	5 (80.0)
Language translation services are available when needed.*	5	5 (71.4)	5 (74.3)	5 (58.8)	5 (80.0)
The identity of the interpreter is documented.	4	4 (31.4)	5 (60.0)	4 (28.6)	5 (75.0)
Patient information is available on all endoscopic procedures performed in the endoscopy unit that conforms to literacy, language, and cultural appropriateness of the patient population cared for by the endoscopy unit.	5	5 (56.3)	5 (65.6)	4 (31.3)	5 (75.0)
The method of provision of information to the patient is documented.	5	5 (51.5)	5 (57.6)	5 (56.3)	5 (75.0)
Endoscopy unit has access to a quiet area that provides privacy for discussions with patients and care partner(s).	5	5 (55.9)	5 (58.8)	4 (23.5)	5 (55.0)
Unit policy discourages the use of family and friends as interpreters.	4	4 (17.1)	4 (28.6)	4 (25.7)	4 (15.8)
Scheduling and appointments	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Patients are informed of their appointment (ie, in person, by mail, phone, or email).	5	5 (79.4)	5 (79.4)	5 (75.8)	5 (85.0)
A preprocedure review is undertaken to screen patients for appropriateness and to communicate with patients about key elements of their procedure.*	5	5 (88.2)	5 (79.4)	5 (73.5)	5 (80.0)
Methods are in place for identifying appropriate surveillance appointment needs, and timely notification and scheduling of appointments is provided.	5	5 (66.7)	5 (57.6)	5 (46.9)	5 (60.0)
Patients and referring physicians are informed of their missed appointments, with commentary regarding the potential health consequences of missed appointments.*	5	5 (54.6)	5 (54.6)	4 (18.2)	4 (35.0)
Data on facility costs and quality are available and transparent to prospective patients, families, and referring physicians.	4	4 (18.2)	5 (51.5)	3 (27.3)	4 (10.0)
Informed consent	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Signatures are obtained on a consent form for all patients who are able to sign the form, and procedures are in place for those who cannot provide consent independently.	5	5 (82.4)	5 (91.2)	5 (87.5)	5 (95.0)
All patients are given an opportunity to ask questions about the procedure before the endoscopy by a professional trained in the consent process.	5	5 (79.4)	5 (76.5)	5 (76.5)	5 (90.0)
Informed consent is obtained and documented by the provider performing the procedure.*	5	5 (79.4)	5 (82.4)	5 (72.7)	5 (80.0)
Unit has a policy to review informed consent forms and process on a regular basis.	5	5 (51.4)	5 (51.5)	4 (15.2)	5 (70.0)

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TABLE 2. Continued

Informed consent	Related to quality	Meaningful to measure (%)	Feasible to measure (%)	Compliance in own endoscopy unit (%)	Related to quality (%)
Published written patient information sheet that includes guidance on frequently asked questions for all procedures (both endoscopic and nonendoscopic) performed in the department is available to patients.	5	5 (52.9)	5 (57.7)	5 (50.0)	5 (65.0)
Endoscopy unit has a written policy for withdrawal of consent during an endoscopic procedure.	4	4 (18.8)	4 (25.0)	3 (33.3)	3 (70.0)
Procedural indications	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
The unit adopts standard indications for endoscopic procedures based upon current national guidelines.*	5	5 (79.4)	5 (75.8)	5 (60.6)	5 (84.2)
Unit policy exists to regularly review the indications for performed procedures according to published list of standard indications.	5	5 (58.8)	5 (52.9)	4 (14.7)	5 (60.0)
Use of an indication or time-to-procedure interval that is outside of accepted standards is clearly documented in the patient's health record.	4	4 (18.2)	4 (27.3)	3 (28.1)	4 (25.0)
Communication of results	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Procedure reports are communicated to referring providers.*	5	5 (90.9)	5 (87.9)	5 (72.7)	5 (95.0)
Pathology reports for patients with cancer are dispatched to referrers after the receipt of the report.*	5	5 (78.8)	5 (75.8)	5 (64.5)	5 (90.0)
Pathology reports are received by the endoscopist (or referrer) responsible for acting upon them within a timely manner.*	5	5 (90.9)	5 (87.9)	5 (81.8)	5 (87.9)
The unit uses a process for timely communication of results to referring providers that complies with HIPAA statutes and other state or federal privacy guidelines.*	5	5 (78.1)	5 (78.1)	5 (64.5)	5 (85.0)
Results (ie, from the endoscopy report) for all inpatients are available in the medical record before the patient leaves the department.	5	5 (54.6)	5 (51.5)	5 (45.5)	5 (72.2)
If the endoscopist has responsibility for taking action or making recommendations based on pathology reports, then the time it takes the endoscopist to act on the results or provide recommendations is tracked.*	5	5 (60.6)	5 (51.5)	4 (18.2)	5 (65.0)
Postprocedure communication/coordination of care	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Patients receive discharge instructions that include recommendations for follow-up, anticoagulation plan, need for antibiotics or other specific therapy (as indicated), and timing of resumption of prior medications.*	5	5 (87.9)	5 (84.9)	5 (81.8)	5 (90.0)
Process in place for patient to receive a copy of the endoscopy report.	5	5 (69.7)	5 (75.8)	5 (66.7)	5 (90.0)

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TABLE 2. Continued

Postprocedure communication/coordination of care	Related to quality	Meaningful to measure (%)	Feasible to measure (%)	Compliance in own endoscopy unit (%)	Related to quality (%)
Communication of results to the patient and/or family is complete and timely, including prompt acknowledgement of recognized adverse events and incomplete or neglected therapies, or sampling.	5	5 (81.8)	5 (78.8)	5 (68.8)	5 (85.0)
Upon discharge from the endoscopy unit, patients are given instructions, both written and verbal, that conforms to literacy and language appropriateness. Instructions document pertinent procedure findings, treatment, contact number in case of emergencies, and follow-up care.*	5	5 (81.3)	5 (78.8)	5 (63.6)	5 (85.0)
Disaster preparedness	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Endoscopy unit maintains a written disaster preparedness plan that provides for the emergency care of all persons in the facility in the event of fire, natural disaster, equipment failure, or other unexpected events or circumstances that are likely to threaten the health and safety, and they coordinate the plan with state and local authorities, as appropriate.*	5	5 (78.8)	5 (84.9)	5 (87.9)	5 (87.9)
Appropriate drills of disaster preparedness plan are performed and documented.	5	5 (66.7)	5 (74.2)	5 (72.7)	5 (87.9)
Ability to provide feedback	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Endoscopy unit has a person or committee responsible for reviewing patient complaints.*	5	5 (78.1)	5 (78.1)	5 (64.5)	5 (85.0)
Basic monitoring and recording of patient comfort and pain levels before, during, and after the procedure.	5	5 (84.9)	5 (84.4)	5 (81.8)	5 (85.0)
Endoscopy unit has a system for gathering patient feedback such as satisfaction surveys, focus groups, or invited comments.	5	5 (84.4)	5 (81.3)	5 (74.2)	5 (80.0)
Actions are planned in response to reported patient complaints.*	5	5 (81.3)	5 (78.1)	5 (67.7)	5 (80.0)
Documented process for adjudicating patient grievances exists on the unit, as required by state or federal law.	5	5 (75.0)	5 (75.0)	5 (68.8)	5 (80.0)
Patients can submit ad hoc patient concerns or positive comments about their care.	5	5 (68.8)	5 (63.6)	5 (60.6)	5 (75.0)
Patient is given realistic expectation that some discomfort may be experienced during the procedure.	5	5 (71.9)	5 (62.5)	5 (62.5)	5 (75.0)
Patient comfort and respect (surveys and nurse records) are reviewed.	5	5 (56.3)	5 (57.6)	5 (56.3)	5 (70.0)
Yield of return from patient satisfaction surveys is tracked and trended.	5	5 (69.7)	5 (75.0)	5 (69.7)	5 (70.0)
Patient comfort and respect results (from surveys and nurse records) are fed back to individual endoscopists and the endoscopy team and are acted upon to ensure issues have been effectively addressed.	5	5 (70.0)	5 (67.7)	5 (54.8)	5 (65.0)

(*continued on the next page*)

TABLE 2. Continued

Ability to provide feedback	Related to quality	Meaningful to measure (%)	Feasible to measure (%)	Compliance in own endoscopy unit (%)	Related to quality (%)
Patient satisfaction surveys include questions regarding the quality of patient information provided.	5	5 (66.7)	5 (66.7)	4.5 (50.0)	5 (65.0)
Accessibility to facilities (ie, parking, way-finding).	4	4 (30.4)	5 (54.6)	5 (51.5)	4 (40.0)
Waiting room amenities are conducive to a positive patient experience (ie, ambiance, WiFi, seating, cleanliness, noise).	4	4 (21.9)	4 (24.2)	4 (39.4)	4 (35.0)

Indicators that are shaded white had consensus reached on them (ie, median of "5" on the second round of voting for the relatedness parameter with >80% of respondents rating it a "5") and were the 6 highest-rated indicators for this domain.
Note: Patients and payers did not participate in the voting process. Both groups were initially invited but opted not to participate.
HIPAA, Health Insurance Portability and Accountability Act of 1996.
*Mandated by national regulatory or accreditation standards.

respondents were located at a hospital-based endoscopy unit (52.9%), followed by ambulatory endoscopy centers (41.8%).

There were 155 potential endoscopy unit quality indicators that were assessed. With regard to the individual parameters related to quality, meaningfulness, feasibility, and current compliance, the majority of potential indicators had a median of "5" (ie, strongly agree) in each of these 4 areas on the first round of voting. 66 quality indicators met our consensus threshold (ie, had a median of "5" with ≥80% of respondents rating it a "5" in the second round of voting). From this list, the highest-rated 6 indicators from each of the 4 domains were selected (1 domain had only 5 indicators that met the consensus threshold), yielding 29 endoscopy unit quality indicators that were included in the final guideline.

Feasibility for measuring endoscopy unit quality indicators

Across all 5 of the domains there was marked variation in perceived feasibility of measuring the proposed quality indicators. Although most quality indicators had a median of "5" in the parameter "Feasible to measure," the percentage of respondents who reported this median ranged from 96.2% to 44.8%. It was well recognized that some indicators are clearly significant and deemed meaningful but are less feasible for measurement and implementation in practice and therefore limited in application. Those that were rated highly with regard to feasibility addressed specific endoscopy unit policies and processes. In contrast, the feasibility of measuring endoscopy unit quality indicators was rated most difficult in areas where data were more detailed, harder to collect, and/or needed to be communicated to staff.

Compliance on measuring endoscopy unit quality indicators

Respondents were asked whether their endoscopy units were compliant with the proposed quality indicators. Again, in each of the 5 domains there was marked variation. Although most potential indicators had a median of "5" in the parameter "Compliance with indicator in their own endoscopy unit," the percentage of respondents who reported this median ranged from 13.3% to 93.3%. Similar to the feasibility results, greater compliance was reported for indicators that addressed specific policies or processes as compared with those that focused on gathering and reporting data.

Patient experience

The patient experience domain incorporated 46 proposed structural and process quality indicators related to 8 subdomains. These subdomains included patients' communication needs and performance, scheduling and appointments, informed consent, procedural indications, communication of results, postprocedure communication and coordination of care, disaster preparedness, and ability to provide feedback. Initially, 23 indicators across the 8 subdomains met the initial consensus threshold with the highest-rated 6 indicators then identified (Table 2). These top 6 quality indicators centered on 3 areas: (1) informed consent (ie, obtaining necessary signatures and answering patients' questions), (2) communication of results, specifically to referring providers, and (3) postprocedure communication to patients about discharge instructions and the process for how patients could receive their endoscopy reports. Among these 6 indicators there was strong agreement during round 1 voting for the "Meaningful to measure" and for "Feasible to measure" parameters. The majority of voters deemed their own units to be in compliance with all 6 of these endoscopy unit quality indicators. Among the originally proposed indicators that did not reach the initial consensus threshold, 16 had a median of 5 ("strong agreement") with less uniformity (<80%), 6 had a median of 4, and 1 had a median of 3 ("neutral") in the second round of voting. None of the proposed indicators had a median of 2 ("disagreement") or 1 ("strong disagreement") on any parameter in both rounds of voting.

TABLE 3. Survey results using the Delphi method to examine potential endoscopy unit quality indicators for the Employee Experience domain

	1st round voting (n = 38), median (%), 1 = strongly disagree, 5 = strongly agree				2nd round voting (n = 30), median (%)
Employee orientation	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Employee orientation process is in place and documented.*	5	5 (64.1)	5 (66.7)	5 (65.8)	5 (70.0)
Current professional physician and nursing practice guidelines and position statements are available.	5	5 (52.6)	5 (50.0)	5 (54.1)	5 (70.0)
Staff are oriented to HIPAA compliance and safety in addition to their job specific tasks.*	5	5 (65.8)	5 (68.4)	5 (81.1)	5 (66.7)
Employee safety	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Staff are up to date on their influenza vaccinations.	5	4.5 (50.0)	5 (84.6)	5 (71.1)	5 (66.7)
Disruptive staff behavior is addressed and resolved.	5	5 (56.4)	4 (43.6)	5 (50.0)	5 (63.3)
Organization provides information on environmental health and safety policies that must be followed in the workplace.*	5	5 (61.5)	5 (69.2)	5 (73.0)	5 (53.3)
Workplace policies include processes to reduce or prevent occupational injuries and illnesses through appropriate training and preventive activities.*	5	4 (41.0)	4 (30.8)	5 (55.3)	5 (53.3)
Employee recognition	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Employee recognition program is in place.	4	4 (34.2)	4 (39.5)	4 (42.1)	4 (36.7)
Employee growth	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Organization provides continuing education opportunities.	5	5 (61.5)	5 (56.4)	4 (43.2)	5 (63.3)
Employees are given opportunities for leadership and promotion.	4	4 (38.5)	4 (41.0)	4 (39.5)	4 (56.7)
Employee feedback	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Unit promotes a culture where staff are empowered to raise concerns about safety and quality in daily operations without fear of retribution.	5	5 (80.6)	4 (18.9)	5 (58.3)	5 (90.0)
Formal staff meetings (including staff and clinic leadership) occur.	5	5 (57.9)	5 (79.0)	5 (57.1)	5 (83.3)
Employees have formal avenues of unit and organizational communication.	5	5 (62.2)	5 (54.1)	5 (52.8)	5 (73.3)
System in place for ongoing and regular feedback from staff on the quality of their work environment.	5	5 (66.7)	5 (51.4)	4.5 (47.2)	5 (70.0)
Employees receive results of employee feedback surveys.	5	5 (48.7)	5 (59.5)	5 (41.7)	5 (63.3)
Employees are invited to provide job satisfaction feedback to their organization.	5	5 (54.1)	5 (62.2)	5 (58.3)	5 (58.6)

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TABLE 3. Continued

Employee feedback	Related to quality	Meaningful to measure (%)	Feasible to measure (%)	Compliance in own endoscopy unit (%)	Related to quality (%)
Employee satisfaction survey results are considered in development of facility/unit plans.	4	4 (36.1)	4 (33.3)	4 (14.7)	5 (55.2)
Process in place for exit interviews to be recorded and/or feedback to clinical and general managers.	4	4 (40.5)	4 (24.3)	4 (16.7)	4 (43.3)
Performance evaluation	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Employees receive individualized performance evaluations with reports.*	5	5 (70.3)	5 (69.4)	5 (62.9)	5 (82.8)
System in place for ongoing and regular feedback to staff on the quality of their work, with periodic formal documentation.	5	5 (71.1)	5 (70.3)	5 (62.2)	5 (75.9)
Action plans are in place to address performance issues identified during appraisal and assessment.	5	5 (52.6)	5 (67.6)	4 (13.5)	5 (75.9)
Rate of unauthorized absenteeism is tracked.	5	5 (37.8)	5 (54.1)	5 (31.4)	5 (62.1)
Average retention rates for employees are tracked and benchmarked.	4	4 (21.6)	5 (54.1)	3 (40.0)	4 (43.3)
Job vacancy rate is tracked.	4	4 (21.6)	5 (54.1)	4 (36.1)	4 (28.6)
Overall and first-year staff turnover rates are tracked.	4	4 (27.0)	5 (55.6)	4 (8.6)	4 (27.6)
Training	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Endoscopy unit has regular education, training programs, and continuous quality improvement for all staff on new equipment/ devices and endoscopic techniques.*	5	5 (76.3)	5 (63.2)	5 (51.4)	5 (90.0)
Team training is used for new techniques/ technology to emphasize communication between providers and nurses.	5	5 (56.8)	4.5 (50.0)	4 (27.0)	5 (86.7)
Staff feedback is considered in development of training programs and in-services.	5	5 (57.9)	4 (26.3)	4.5 (47.2)	5 (83.3)
Endoscopy unit uses training checklists to maximize training opportunity for low-volume procedures.	5	5 (68.4)	5 (62.2)	4 (13.5)	5 (80.0)
Training includes emphasis on trouble-shooting commonly experienced and high-risk problems.	5	5 (63.2)	5 (52.6)	4 (27.0)	5 (80.0)
Training programs are competency-based and modified in response to staff feedback.	5	5 (63.2)	5 (52.6)	4 (26.5)	5 (80.0)
Trainers are competent for what they teach and a mechanism is in place to assess their ability to teach.	5	5 (63.2)	4 (29.0)	4 (35.1)	5 (80.0)
Identified staff member coordinates training checklists.	5	5 (55.3)	5 (55.3)	4 (32.4)	5 (66.7)

Indicators that are shaded white had consensus reached on them (ie, median of "5" on the second round of voting for the relatedness parameter with ≥80% of respondents rating it a "5") and were the 6 highest-rated indicators for this domain.
Note: Patients and payers did not participate in the voting process. Both groups were initially invited but opted not to participate.
*Mandated by national regulatory or accreditation standards.

TABLE 4. Survey results using the Delphi method to examine potential endoscopy unit quality indicators for the Efficiency and Operations domain

	1st round voting (n = 35), median (%), 1 = strongly disagree, 5 = strongly agree				2nd round voting (n = 25), median (%)
Leadership/strategic planning	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Endoscopy unit has a defined leadership structure.*	5	5 (66.7)	5 (83.3)	5 (77.8)	5 (92.0)
Designated individual within the leadership hierarchy oversees quality.*	5	5 (66.7)	5 (69.4)	5 (61.1)	5 (84.0)
Mission statement incorporates and physician leadership champions a "culture of quality."	5	5 (61.1)	4 (30.6)	5 (63.9)	5 (76.0)
Endoscopy unit participates in formal quality benchmarking.	5	5 (63.9)	5 (63.9)	4 (37.1)	5 (72.0)
Staff participates in appraisal of unit policies and daily operations and are encouraged to suggest improvements.	5	5 (75.0)	5 (61.1)	5 (61.1)	5 (72.0)
Endoscopy unit has a process in place to address unexpected operational challenges in a timely manner.	5	5 (58.3)	4 (41.7)	4 (37.1)	5 (68.0)
Endoscopy unit has a practice administrator with advanced business training or experience.	4	3 (27.8)	4 (27.8)	5 (50.0)	4 (48.0)
Endoscopy unit leadership has an annual strategic planning meeting.	4.5	4 (25.0)	5 (63.9)	4 (28.6)	4 (32.0)
Operations	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Endoscopy unit adheres to regulatory requirements, including federal, state, local, and institutional, with respect to facilities and operating space.*	5	5 (83.3)	5 (83.3)	5 (91.7)	5 (87.5)
Endoscopy unit has a policy on administering monitored anesthesia care (MAC) and moderate sedation.	5	5 (64.7)	5 (61.1)	5 (51.4)	5 (87.5)
Unit committee(s) structure includes effective governance with physician and other stakeholder participation.	5	5 (86.1)	5 (85.7)	5 (88.6)	5 (84.0)
Endoscopy unit has a quality assurance committee that develops and enforces quality standard policies, meets regularly, generates quality reports for the endoscopy center and leadership, and manages quality improvement projects.*	5	5 (80.6)	5 (63.9)	5 (69.6)	5 (72.0)
Unit has a process in place to regularly trend and adjust resource availability, including equipment, space, time, and staff (eg, procedures/room/day, number of endoscopes/room)	5	5 (58.3)	5 (61.8)	4 (31.4)	5 (68.0)
Endoscopy unit has a policy on the formal review and evaluation for new devices and equipment.*	5	5 (55.6)	5 (58.3)	4 (33.3)	5 (68.0)
Endoscopy unit staff (eg, technician, nurse) are cross-trained.	5	5 (65.7)	5 (63.9)	5 (72.2)	5 (64.0)
Key intervals of patient throughput in the endoscopy unit are measured (eg, room turnover time, recovery time).	5	4 (47.2)	5 (66.7)	4 (42.9)	5 (60.0)

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TABLE 4. Continued

Operations	Related to quality	Meaningful to measure (%)	Feasible to measure (%)	Compliance in own endoscopy unit (%)	Related to quality (%)
Rate of "no shows" and canceled appointments or procedures.	4	5 (52.8)	5 (66.7)	5 (52.8)	5 (56.0)
Endoscopy unit has a policy for late-arriving staff (including physicians).	5	5 (55.9)	5 (58.8)	4 (20.0)	4 (32.0)
Endoscopy unit has a policy for late-arriving patients.	4	4 (30.6)	4 (31.4)	3 (30.6)	4 (28.0)
Rate of on-time first case start.	4	4.5 (50.0)	5 (66.7)	4 (25.2)	4 (28.0)
Rate of room turnover time (case complete to next case start time).	4	4 (30.6)	5 (63.9)	5 (54.3)	4 (28.0)
Timeliness	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Time from procedure request to procedure date for routine procedures is tracked.	4	4 (38.9)	4 (22.9)	3.5 (19.4)	4 (28.0)
Endoscopy unit has a system in place to classify endoscopy referrals into emergent, urgent, and routine categories.	5	5 (47.2)	4.5 (44.4)	4.5 (36.1)	4 (20.8)
Endoscopy wait times are communicated to the endoscopy team and made available to referring physicians.	4	4 (27.8)	4 (13.9)	3 (23.5)	3 (28.0)
Wait time for urgent and semiurgent (within 24 hours) procedures.	4	4 (20.6)	4 (25.7)	3 (31.4)	3 (28.0)

Indicators that are shaded white had consensus reached on them (ie, median of "5" on the second round of voting for the relatedness parameter with ≥80% of respondents rating it a "5") and were the 6 highest-rated indicators for this domain.
Note: Patients and payers did not participate in the voting process. Both groups were initially invited but opted not to participate.
*Mandated by national regulatory or accreditation standards.

Overall patient experience quality indicators were rated highly with respect to the feasibility of their measurement, with 41 of 46 indicators having a median of 5. Lower scores for "own unit compliance" were more closely associated with the excluded indicators on round 2 voting than were lower scores for "relatedness to quality," "meaningful to measure," or "feasible to measure." Indicators receiving lower compliance ratings and considered by the respondents to be less related to quality included: making data on facility costs and quality available, documentation in the patient's health record of indications or surveillance intervals that depart from recommendations or guidelines, and maintenance of a written policy for withdrawal of consent during a procedure.

Research questions

- To what extent does "documentation," as opposed to performance measurement, stimulate improvement, or enhance care?
- Can language barriers in written and verbal communication be overcome with acceptable quality at tolerable expense?
- Do written and verbal informed consent processes provide adequate patient and family understanding of the true risks, alternatives, and rates of adverse events?
- Once indicators pertaining to processes are established, how should an endoscopy unit measure its performance on the indicator?
- How can endoscopy unit quality programs (EUQPs) evaluating patient experience best develop, select, and measure indicators that are patient identified, accurately measure our patients' actual health care encounter experience, and address those concerns that are of greatest importance to our patients?
- Can the GI professional societies facilitate standardized and benchmarked unit quality programs by developing a web-based program modeled on the GRS and Gastrointestinal Quality Unit Improvement Consortium (GIQuIC)?
- To what extent do patient experience quality indicators correlate with other indicators of traditional quality outcomes in endoscopy?

Employee experience

There were 33 potential endoscopy unit quality indicators that were originally developed by expert consensus in the employee experience domain. This domain was further subdivided into areas that covered employee feedback, performance evaluation, training, employee orientation, employee safety, employee recognition, and employee growth. Initially, 10 of those indicators that were proposed met our consensus threshold, of which the 6 top rated indicators were highlighted (Table 3). Among these 6 quality indicators, all had a median of

TABLE 5. Survey results using the Delphi method to examine potential endoscopy unit quality indicators for the Procedure-Related domain

	1st round voting (n = 30), median (%), 1 = strongly disagree, 5 = strongly agree				2nd round voting (n = 22), median (%)
Preprocedure	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Endoscopy unit has a process to ensure that all elements of the preprocedure assessment are documented before the procedure begins.	5	5 (86.7)	5 (82.8)	5 (83.9)	5 (90.9)
Preprocedure process is reviewed by clinic leadership on a regular basis.	5	5 (62.1)	5 (62.1)	5 (69.0)	5 (71.4)
Preprocedure space is monitored to ensure that it meets patient and staff needs and is clean, functional, quiet, ensures patient privacy, and has amenities conducive to a positive patient experience.	5	5 (66.7)	4 (23.3)	5 (67.7)	5 (61.9)
Patients and families are kept informed about procedure-related wait to manage expectations.	4	4 (22.6)	5 (48.4)	5 (46.9)	4.5 (50.0)
Procedure	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Mechanism(s) are in place to detect, assess, and address concerns raised regarding physicians' competence.	5	5 (89.7)	5 (75.9)	4 (17.2)	5 (86.4)
Endoscopy unit records, tracks, and monitors procedure quality indicators for both the endoscopy unit and individual endoscopists.	5	5 (89.7)	5 (75.9)	5 (62.1)	5 (86.4)
Unit has policy in place for patient pause/time-out that satisfies all key elements.*	5	5 (90.0)	5 (82.8)	5 (93.3)	5 (82.8)
Endoscopy unit has a privileging policy and committee to make decisions that a physician's training and performance is in accordance with nationally accepted indicators.*	5	5 (85.7)	5 (82.1)	5 (58.6)	5 (81.8)
Data on quality indicators are communicated to staff and endoscopists.	5	5 (89.7)	5 (81.8)	5 (53.6)	5 (81.8)
Endoscope and accessories used in a procedure are identified in a procedure record.*	5	5 (69.0)	5 (69.0)	5 (75.9)	5 (81.8)
Endoscopy unit develops quality improvement projects that address indicators which are below targets.	5	5 (78.6)	5 (75.9)	5 (60.0)	5 (81.8)
Peer review of procedures by endoscopists is performed.	5	5 (80.0)	5 (82.8)	4 (10.3)	5 (77.3)
ERCP volume and sphincterotomy volume by physician and unit are tracked and considered for privileging.	5	5 (41.3)	5 (44.8)	5 (13.3)	5 (57.9)
Rate of scheduled procedures cancelled/rescheduled by provider.	5	5 (51.7)	5 (56.7)	4 (20.7)	5 (52.4)
Rate of scheduled procedures cancelled/rescheduled by patient.	4	4 (10.3)	5 (55.2)	4 (20.7)	4.5 (50.0)
Postprocedure	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Unit has a policy on reconciliation of specimen requisition to ensure physician and staff agree on specimen labeling.*	5	5 (90.0)	5 (82.8)	5 (86.2)	5 (95.5)
Patients are not discharged unless formal discharge criteria are met.*	5	5 (89.3)	5 (85.7)	5 (86.2)	5 (86.4)

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TABLE 5. Continued

Postprocedure	Related to quality	Meaningful to measure (%)	Feasible to measure (%)	Compliance in own endoscopy unit (%)	Related to quality (%)
Recovery space is clean, functional, quiet, ensures patient privacy, has adequate postprocedure monitoring for patients, and has amenities conducive to a positive patient experience.	5	5 (75.9)	5 (69.0)	5 (79.3)	5 (81.8)
Rate of hospital admissions after procedure.	5	5 (79.3)	5 (75.9)	5 (66.7)	5 (77.3)
Patient has an opportunity to speak with the provider who performed the procedure before discharge.	5	5 (69.0)	5 (55.2)	5 (64.3)	5 (77.3)
Unit has a policy in place for postprocedure follow-up call.	5	5 (72.4)	5 (75.9)	5 (73.3)	5 (77.3)
Rate of mislabeled/missing pathologic specimens.	5	5 (82.8)	5 (75.9)	5 (69.0)	5 (77.3)
Unit has a policy in place for lack of a responsible adult patient escort after procedure.*	5	5 (69.0)	5 (69.0)	5 (83.3)	5 (72.7)
Success rate of patient follow-up call after procedure.	5	5 (58.6)	5 (65.0)	5 (53.3)	5 (54.6)

Indicators that are shaded white had consensus reached on them (ie, median of "5" on the second round of voting for the relatedness parameter with >80% of respondents rating it a "5") and were the 6 highest-rated indicators for this domain.
Note: Patients and payers did not participate in the voting process. Both groups were initially invited but opted not to participate.
*Mandated by national regulatory or accreditation standards.

5 in the parameter of "Meaningful to measure," whereas 3 of these indicators had a median of 5 for "Feasible to measure" during round 1 voting. One third of respondents deemed their own units to be out of compliance with these 6 indicators. By contrast, among the originally proposed indicators that did not meet our initial consensus threshold, 17 had a median of 5 with less uniformity (<80%) and 6 had a median of 4 in the second round of voting. None of the proposed indicators had ratings for "disagreement" or "strong disagreement" on any parameter.

Several themes emerged among the top rated 6 quality indicators for employee experience. For example, half of these indicators underscored the important relationship between training and overall employee experience. Respondents agreed that endoscopy units should provide regular education programs and continuous quality improvement for all staff on new equipment/devices and endoscopic techniques, using tools such as checklists and team training. Furthermore, this training should be competency based, modified in response to staff feedback, and provided by competent trainers. One third of the 6 indicators valued the importance of employee feedback. In this arena, respondents thought that high-quality endoscopy units should foster a culture wherein staff feel empowered to raise concerns about the safety and quality of the endoscopy unit and that there were formal staff meetings. Finally, 1 indicator reflected the importance of performance evaluations and formalized goal setting for employees.

Research questions

- Is there a correlation between employee experience and other measures of endoscopy unit quality?
- Is there a relationship between the quality of the education and a quality outcome (eg, education on endoscope reprocessing and subsequent compliance with all steps)?
- Is there a relationship between the manager/supervisor performance and the quality of employee experience?
- Is there a relationship between physician attitudes and the overall quality of the endoscopy unit?
- What are ways to improve compliance for education and training quality indicators that are rated as meaningful and feasible?
- What is the relationship between employee recognition programs and the overall quality of the unit?
- What are the important opportunities for leadership and professional growth in the endoscopy unit?
- What durations of training are required for safe and independent performance in specific roles within the endoscopy unit?
- How effective are efforts to enhance staff satisfaction/training in improving patient satisfaction and other procedure outcomes?

Efficiency and operations

In the efficiency and operations domain, 25 potential endoscopy unit indicators were originally developed by expert consensus. They primarily addressed endoscopy unit and individual leadership, endoscopy unit efficiency, and specific endoscopy unit policies, and were organized into 3 subdomains of leadership/strategic planning, operations, and timeliness. Five indicators met our consensus threshold on the second round of voting (Table 4). All 5 of these indicators had a median of 5 in the parameter of "Meaningful to measure," "Feasible to measure," and

TABLE 6. Survey results using the Delphi method to examine potential endoscopy unit quality indicators for the Safety and Infection Control domain

	1st round voting (n = 29), median (%), 1 = strongly disagree, 5 = strongly agree				2nd round voting (n = 18), median (%)
Safety	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Nurses and physicians are credentialed with endoscopy unit policy relative to moderate sedation.*	5	5 (82.1)	5 (85.7)	5 (85.7)	5 (92.3)
Endoscopy unit has a written environmental disinfection policy.	5	5 (81.5)	5 (85.2)	5 (76.9)	5 (92.3)
Endoscopy unit has a system for reviewing adverse events and implementing strategies to prevent or reduce them.*	5	5 (92.3)	5 (77.8)	5 (71.4)	5 (83.3)
Presence of all sedation reversal agents is verified each day the facility is in operation.*	5	5 (64.3)	5 (75.0)	5 (75.0)	5 (83.3)
Endoscopy unit has a system for monitoring that all medical equipment, including rescue devices, are in proper working condition, and this is verified each day the facility is in operation.*	5	5 (75.0)	5 (85.7)	5 (66.7)	5 (83.3)
Resuscitation equipment, availability, and functional status are verified each day the facility is in operation.*	5	5 (82.1)	5 (92.9)	5 (82.1)	5 (82.4)
Endoscopy unit has written policies detailing safety procedures in the facility.	5	5 (57.1)	5 (75.0)	5 (67.9)	5 (72.2)
Endoscopy unit has a system for recording and tracking endoscopy-related adverse events.*	5	5 (89.3)	5 (67.9)	5 (71.4)	5 (72.2)
Endoscopy unit has a process in place to identify patients at risk for falls.*	5	5 (53.6)	5 (57.1)	5 (57.1)	5 (72.2)
Rate of unplanned admissions, emergency department visits, and observation stays within 7 days after receiving a colonoscopy.	5	5 (69.2)	4 (48.2)	2 (22.2)	5 (66.7)
Use of reversal agents for sedation is documented and tracked on a regular basis.*	5	5 (64.3)	5 (81.5)	5 (64.3)	5 (61.1)
Rates of modification, interruption, or termination of scheduled procedures because of sedation-related events.*	5	5 (60.7)	5 (64.3)	4.5 (50.0)	5 (61.1)
Number of adverse events that occur within 14 days of an endoscopic procedure including in-hospital deaths and nonelective hospital admissions is recorded.	5	5 (64.3)	5 (51.9)	4 (14.3)	5 (33.3)
Mechanism in place to contact patients 14 to 30 days after their procedure to identify delayed adverse events.	5	4 (25.0)	4 (17.9)	2 (14.3)	4 (27.8)
Infection control	**Related to quality**	**Meaningful to measure (%)**	**Feasible to measure (%)**	**Compliance in own endoscopy unit (%)**	**Related to quality (%)**
Process is in place to track each specific endoscope from storage, use, reprocessing, and back to storage.	5	5 (82.1)	5 (78.6)	5 (85.7)	5 (94.4)
Endoscopy unit has instructions immediately available for high-level disinfection that are specific to the endoscope models being used.*	5	5 (85.7)	5 (89.3)	5 (81.5)	5 (94.4)

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TABLE 6. Continued

Infection control	Related to quality	Meaningful to measure (%)	Feasible to measure (%)	Compliance in own endoscopy unit (%)	Related to quality (%)
Endoscopy unit has policies and procedures in place to ensure that reusable medical devices are cleaned and reprocessed in accordance with manufacturer's instructions appropriately before use in another patient.*	5	5 (88.9)	5 (85.2)	5 (78.6)	5 (94.4)
Endoscopy unit has policies and procedures in place to identify damaged equipment and remove that equipment from service.*	5	5 (75.0)	5 (75.0)	5 (66.7)	5 (94.4)
Process is in place to maintain a log on the successful completion of each key step in reprocessing, including sufficient patient demographic information and endoscope identification for appropriate postprocedure event.	5	5 (85.2)	5 (84.6)	5 (84.6)	5 (88.9)
Endoscopy unit has a specific policy discussing the proper use of single-dose medication vials.	5	5 (75.0)	5 (85.7)	5 (71.4)	5 (88.9)
Endoscopy unit has policies and procedures that adhere to current ASGE and SGNA guidelines concerning safety and infection control in endoscopy.	5	5 (82.1)	5 (85.7)	5 (70.4)	5 (88.9)
Endoscopy unit has policies and procedures in place to ensure the proper use of devices marked single use only.	5	5 (78.6)	5 (82.1)	5 (82.1)	5 (88.9)
Policy to avoid the use of multidose vials when possible and document their appropriate use when they are used.	5	5 (77.8)	5 (77.8)	5 (74.1)	5 (88.9)
Handwashing facilities and alcohol-based hand gel are available to patients, visitors, and staff.	5	5 (78.6)	5 (78.6)	5 (85.2)	5 (88.9)
Core competencies for personnel involved in reprocessing endoscopes are verified initially and at least annually or when there is an adverse event or change in endoscopes or reprocessing equipment.*	5	5 (85.2)	5 (96.2)	5 (84.6)	5 (88.2)
Endoscopy unit monitors and records adherence to hand hygiene guidelines and provides feedback to personnel.	5	5 (67.9)	5 (60.7)	5 (64.3)	5 (77.8)
Process is in place to document the successful completion of training in safe injection practices, and then verification of compliance of all personnel regarding safe injection practices on a semiannual basis.	4	4 (21.4)	4 (32.1)	3.5 (17.9)	4 (22.2)

Indicators that are shaded white had consensus reached on them (ie, median of "5" on the second round of voting for the relatedness parameter with ≥80% of respondents rating it a "5") and were the 6 highest-rated indicators for this domain.
Note: Patients and payers did not participate in the voting process. Both groups were initially invited but opted not to participate.
ASGE, American Society for Gastrointestinal Endoscopy; *SGNA*, Society of Gastroenterology Nurses and Associates.
*Mandated by national regulatory or accreditation standards.

"Compliance in own endoscopy unit." These indicators tended to concentrate on leadership in the endoscopy unit, with a particular emphasis on its structure and governance, and also focused on quality and meeting regulatory requirements.

Among the 20 original quality indicators that did not meet our initial consensus threshold, 10 had a median of 5 with less uniformity (<80%), 8 had a median of 4, and 2 had a median of 3 in the second round of voting. None of the proposed indicators received "disagreement" or "strong disagreement" on any parameter. Additionally, respondents deemed that several important indicators were not feasible to measure and that their endoscopy units were noncompliant. These included the following: that the endoscopy unit has a policy for late arriving patients, wait times for urgent and semiurgent procedures are

tracked, and wait times are communicated to the endoscopy team and made available to referring physicians.

Research questions

- What methods are there to foster/develop physician and administrative endoscopy unit leadership skills?
- What methods should be used to identify a "physician champion" for the endoscopy unit quality program?
- What methods should be developed to implement a "quality culture" at all levels of patient care and delivery of services within an endoscopy unit?
- How do efficient practices correlate with specific patient satisfaction measures and other procedure-related outcomes?

Procedure-related

In the procedure-related domain, 24 quality indicators were originally developed. This domain was further divided into 3 subdomains: preprocedure, procedure, and postprocedure. Among these 3 subdomains, 11 quality indicators met our initial consensus threshold. Among the highest-rated 6 indicators in this group, all had a median of 5 during the first round of voting for both "Meaningful to measure" and "Feasible to measure" with only 1 of these indicators not having a median of 5 in the "Compliance in own endoscopy unit" parameter (Table 5). Moreover, several themes were observed among these 6 highlighted procedure-related quality indicators, which included the preprocedure processes (eg, preprocedure assessment, patient pause/time out) and postprocedure processes (eg, discharge criteria, pathology specimen reconciliation), assessing and addressing physician competence, and quality measurement and improvement.

Among the 13 originally proposed quality indicators that did not meet our initial consensus threshold, 11 had a median of 5 with less uniformity (<80%) with 2 having a median of 4.5 on the second round of voting. None of the potential indicators in the procedure-related domain received ratings of neutral, disagreement, or strong disagreement on any of the 4 measured parameters. Additionally, an overwhelming majority of proposed procedure-related quality indicators scored highly as they related to quality, meaningfulness, and feasibility with most respondents reporting that their endoscopy units were currently compliant with all of these indicators. Yet, 2 main areas scored lower in terms of endoscopy units currently being compliant with proposed indicators: (1) assessing competence of endoscopists, specifically having a process in place to detect and address endoscopists' competence and performing peer review of procedures by endoscopists, and (2) measuring the rate of scheduled procedures cancelled/rescheduled by both the patient and the provider.

Research questions

- What is the exact rate of mislabeled specimens obtained in endoscopic procedures?
- What is the optimal and efficient method for collecting data on procedure quality indicators?
- How should the privileging and credentialing process be used to maintain and improve quality in the endoscopy unit, and how does this process influence procedure outcomes?
- What is the optimal process for endoscopy units to maintain and aggregate endoscopist-specific data on behalf of individual practitioners?

Safety and infection control

In this domain, 27 quality indicators were originally developed and were divided into 2 subdomains: safety and infection control. These proposed indicators included issues related to endoscopy equipment and its handling and issues related to personnel and training in safety and infection control. Seventeen indicators across both subdomains met our initial consensus threshold. The highest-rated 6 indicators from this domain were then identified (Table 6). Among these 6, all had a median of 5 for the "Meaningful to measure," "Feasible to measure," and "Compliance in own endoscopy unit" during round 1 voting. The core elements of these top 6 indicators focused on disinfection and maintenance of endoscopic equipment and associated devices and the credentialing of staff (including physicians and nurses) with regard to moderate sedation.

Among the 10 originally proposed indicators that did not meet our initial consensus definition, 8 had a median of 5 with less uniformity (<80%), and 2 had a median of 4 on the second round of voting. None of the proposed indicators received strong disagreement on any parameter. Importantly, nearly all of the proposed quality indicators were rated highly with respect to the "Related to quality" parameter on both rounds of voting, and most respondents reported compliance within their own endoscopy units, showing that indicators of high-quality safety and infection control practices in endoscopic facilities are now well recognized and being practiced.

Several indicators were judged to be of significant importance, but ultimately were thought to be less feasible to measure and were among those that were rated lower in terms of compliance. Indicators in this category included the following: mechanisms are in place to contact patients regarding any adverse event after a procedure, and tracking the rate of unplanned admissions/emergency rooms visits for patients who had undergone a colonoscopy. It was well recognized that some safety and infection control indicators may be clearly of significance, and deemed to be meaningful, but ranked as not feasible to be put into easy practice and therefore possibly limited in practical application.

Research questions

- What systems can be incorporated into the current data collection programs (eg, endoscopy report–generating software) to capture essential indicators on safety and infection control without undue burden?

- How would vendor participation in designing and maintaining systems for capturing essential indicators on safety and infection control improve data collection?
- What is/are the best method(s) for capturing information on delayed adverse events?
- What is/are the best approach(es) to collate, trend and remediate adverse events?
- What is/are the best method(s) for tracking and trending unplanned admissions/emergency room visits after procedures?

DISCUSSION

Through a comprehensive process that consisted of an extensive literature review and soliciting expert opinion, 155 proposed endoscopy unit quality indicators were developed. These proposed quality indicators spanned 5 domains, which included patient experience, employee experience, efficiency and operations, procedure-related endoscopy unit issues, and safety and infection control. Subsequently, to reach consensus on which indicators to include in this guideline a modified Delphi method was used and identified 29 quality indicators related to the quality of an endoscopy unit. This represents the first effort in which quality indicators have been identified for U.S. endoscopy units, and it serves as a tool by which endoscopy units can begin to measure and improve their quality, initiate the process of benchmarking these indicators, and further determine which indicators are closely aligned with patient outcomes.

Patient experience

Consistent with the national adoption of patient experience indicators and reporting mechanisms, numerous studies of patient satisfaction and experience have been performed to assess their correlation with variables of care. Through this work a number of factors have been associated with greater patient satisfaction in endoscopy units. Such factors include the staff's personal manner, technical skill of the endoscopist, endoscopy unit environment, clear communication from the endoscopist both before and after the procedure, and prompt access to endoscopic services.[17,18] Additionally, the importance of pain control and patient experience at an endoscopy unit has been widely reported, with the correlation between the 2 varying among studies. In fact, recent data suggest a surprising inverse relationship between patient comfort and dosing of moderate sedation, but directly correlated with outcomes of adenoma detection and cecal intubation rates.[19] Many of the quality indicators identified in this guideline serve to monitor and measure many of these factors with the goal of ultimately improving them.

At the same time, none of the studies on patient experience have developed or evaluated patient-reported outcome or experience measures (ie, generated from the patients' perspective), which are now recognized to be an increasingly important element of validity.[20] For example, a recent meta-analysis identified that most studies have varied between a focus on the generation of new endoscopy-specific patient experience measures versus modification or validity testing of existing measures, and that most patient experience measures are derived from a clinician's perspective.[21] Finally, although it is important to ensure that patients have a positive healthcare experience, it does remain unclear whether higher patient satisfaction results in better outcomes for patients.[22] In the future, other measures of patient satisfaction and experience will likely be developed and be correlated with accepted quality outcomes in endoscopy. Finally, future work will need to focus on developing and validating interventions aimed at improving the patient experience in endoscopy units.

Employee experience

Although patient satisfaction is well accepted as a quality metric in medicine, employee engagement and experience has been less well explored. Existing literature in the healthcare and nonhealthcare industries demonstrates a direct and positive relationship between patient/customer experience and employee engagement and performance. In healthcare, overall employee workplace experience has tangible consequences, including the successful recruitment and retention of skilled employees. Furthermore, the link between employee engagement and patient satisfaction ultimately affects the quality of patient care.[23-48] Research published by well-known organizations, including Gallup and Press Ganey, demonstrates the direct correlation between patient and employee experience. However, to date, there are limited studies that identify specific indicators measuring employee experience in GI and endoscopy unit settings in the United States.[37,40,49-54] Much of the literature on employee experience in healthcare has examined promoting high-level leadership practices,[55] having a strong relationship with and support from managerial staff, organizational commitment,[56,57] work content that is valued by the employee, and workplace environment.[58,59] Improvements in these areas leads to improved staff retention, less absenteeism, improved team communication, and greater patient satisfaction. Our current study provides one of the first attempts to identify quality indicators as they pertain to employee experience in the endoscopy unit and builds on many of these key concepts noted in the literature. Key indicators identified through our approach highlight that staff empowerment through meetings; ongoing performance evaluations; and training that is continuous, team-based, and modified on the basis of staff feedback are essential to measure, track, and improve on within the endoscopy unit. By measuring employee experience, an endoscopy unit can better understand and implement strategies to

improve employee, and therefore patient, experience and thus the overall quality of the unit.

Efficiency and operations

In the current healthcare environment, value is best defined by the delivery of efficient and high-quality healthcare. Although the study of efficiency has been the focus of management in many industries, incorporating efficiency models into healthcare has occurred only recently. In the United States there are few evidence-based publications evaluating operations and efficiency in GI endoscopy[60-62] and only 1 of these was performed during a time period that represents the current environment of endoscopic practice in the United States. These articles; an expert, opinion-based review article[63]; and previous operations research conducted by the ASGE and the Medical Group Management Association provided the foundation that was used to develop the categories within the domain of efficiency and operations. Our indicators offer the first attempt to expand on and refine this expert opinion and also construct a framework by which endoscopy units can begin to more consistently measure and track their operations management and efficiency. Having a defined and inclusive leadership with a focus on meeting regulatory requirements with regard to space and operations appeared to be areas of greatest agreement among respondents in our study. Given that these quality indicators and the majority of others in this domain were process measures with little supporting data from the literature, future studies aimed at developing more outcome-based indicators are needed.

Procedure-related

There has been a dramatic rise in the request for GI specialty care in the United States, in particular endoscopic services, over the past 3 decades.[64-66] In parallel, multiple quality indicators for various endoscopic procedures have been identified.[1-5] However, these indicators have been focused on individual providers and specific procedures rather than on how they relate to or impact the endoscopy unit. Our study addressed this observation by focusing on procedure-related indicators and how they impact the quality of an endoscopy unit. From our data we discovered several important indicators in the preprocedure, intraprocedure, and postprocedure processes in the endoscopy unit.

Few studies are available that have examined procedure-related quality indicators for endoscopy units. Furthermore, indicators that have been reported in this domain are overwhelmingly process measures with little supporting data. Much of the literature on procedure-related quality indicators has focused on aspects of the preprocedure and postprocedure process. For example, documenting and performing endoscopic procedures for an appropriate indication increases the diagnostic yield of findings during endoscopy and decreases inappropriate use[67-70]; improved safety outcomes have been demonstrated for performing a patient pause/time-out immediately before the beginning of a procedure[71-75]; and the use of validated, standardized discharge criteria has documented benefits in safely discharging patients home after a procedure.[76-79] Likewise, intraprocedural quality indicators have been enumerated; monitoring[1-3,5] and communicating[80] data on quality indicators to providers performing endoscopic procedures has resulted in improved quality and reduced practice variation among providers. Not surprisingly, some of the highest-rated indicators in the procedure-related domain from our study correlated with work from the published literature. However, much of the literature on procedure-related quality indicators for endoscopy units is based on expert opinion. Areas such as privileging and credentialing for performing procedures,[4,12,81-85] obtaining/documenting informed consent,[6,10] performing a preprocedure assessment,[4,86,87] and providing discharge instructions to patients,[4,10] although identified as important procedure-related quality indicators, have no patient outcomes-related data available to date. This void in robust studies examining outcomes with regard to procedure-related quality indicators highlights the need for continued research in this area.

Safety and infection control

Safety and infection control are of paramount importance to the overall success and efficacy of GI endoscopy. Consequently, performance assessment of endoscopic units must include measures designed to evaluate these elements. Infections related to GI endoscopy are rare events, and most have been related to breaches in established protocols for handling and reprocessing endoscopes. In line with this and concordant with ASGE guidelines, indicators deemed of highest importance in the safety and infection control domain were related to the proper training of staff and having policies and processes in place to ensure maintenance of adequate infection control in the endoscopy unit. Safety and infection control in endoscopic facilities have been the topic of many reviews and guidelines[88,89] and recently have been the focus of media headlines, with patients experiencing carbapenem-resistant Enterobacteriaceae infections after undergoing ERCP.[90] Multiple individual guidelines exist on infection control in endoscopy,[91] adequate room staffing,[92] sedation in endoscopy,[87] and quality indicators in GI endoscopy.[4] Although several guidelines in this area exist, in general many requirements for safety and infection control have little supporting outcomes data. Instead, such recommendations come from consensus by experts with experience in the safe delivery of care in the GI endoscopy setting. Continued work in this area will likely be centered on the development and study of more outcome-based indicators, with supporting benchmark data to help guide improvement work in endoscopy units.

PRIORITY INDICATORS FOR A HIGH-QUALITY ENDOSCOPY UNIT

This guideline provides the first comprehensive list of quality indicators for U.S. endoscopy units. Our rigorous process of examining the available literature, leveraging the knowledge of experts in the field, and soliciting feedback from endoscopy unit stakeholders yielded 155 indicators across 5 key domains, of which we discuss 29 of the highest-rated indicators. Yet, given the large number of quality indicators proposed, we wanted to highlight 5 endoscopy unit quality indicators from among this list that were considered the most compelling to measure and track for a high-quality endoscopy unit. The taskforce selected these priority indicators using the following criteria:

- Existing support in the literature for an association with improved patient outcomes
- Consensus among the taskforce members that performance gaps and variation existed

These 5 priority endoscopy unit quality indicators include:

- Endoscopy unit has a defined leadership structure.
- Endoscopy unit has regular education, training programs, and continuous quality improvement for all staff on new equipment/devices and endoscopic techniques.
- Endoscopy unit records, tracks, and monitors procedure quality indicators for both the endoscopy unit and individual endoscopists.
- Procedure reports are communicated to referring providers, and a process is in place for patients to receive a copy of their endoscopy report.
- Process is in place to track each specific endoscope from storage, use, reprocessing, and back to storage.

These priority indicators reflect the key elements of a high-quality endoscopy unit, and several of them span many of the domains discussed in this guideline. First, ensuring that a defined leadership is in place helps to promote high-performance leadership and organizational commitment, which not only magnifies efficiency and operations of the endoscopy unit but advances staff experience. Second, promoting education and training among staff and endoscopists, and monitoring and providing feedback on their performance, not only stimulates professional development but helps ensure that patients undergoing endoscopic procedures are receiving high-quality and safe care. Third, communication with patients and referring providers about a patient's care within the endoscopy unit helps foster a more patient-centered environment, thereby improving the patient experience and improves transitions in care. Finally, embedded within a high-quality endoscopy unit is a culture of safety and high standards for infection control; central to this theme are practices and policies along with monitoring related to endoscope reprocessing. Although these elements are the foundation of a high-quality endoscopy unit, they are by no means complete and all-inclusive. These priority indicators should be considered a starting point from which an endoscopy unit could build on during ongoing quality improvement efforts.

LIMITATIONS

Several limitations exist with our method. Selection bias was present because respondents were a highly motivated and engaged group. Although patients and payers were invited to participate, our voting sample did not include these representatives. Moreover, our response rate of 22.2% is low and can impact the generalizability of our results. Our respondents' interpretation of whether an indicator was related to quality may have been influenced by their own endoscopy units' experience and compliance. Our proposed indicators do not establish formal measure definitions or performance thresholds. The latter is currently limited because of the lack of adequate methods for benchmarking these parameters in practices across the country. The majority of the quality indicators included in the study were process and structural measures; many require development of systems for data gathering and tracking. We acknowledge and anticipate variability in measurement across different practice settings. Last, many of the quality indicators in the survey received high ratings that ultimately did not meet our predefined consensus threshold; it is for this reason that all potential endoscopy unit quality indicators queried appear in the tables.

CONCLUSION

A lack of information on the performance variation among endoscopy departments, and the lack of a current organizational framework by which endoscopy units can direct their quality improvement efforts, suggest a need for evidence-based quality indicators targeted at the endoscopy unit level. Using the Delphi method to establish consensus among leaders in U.S. endoscopy units, we evaluated proposed indicators for endoscopy unit quality. This survey, the first of its kind in the United States, was comprehensive in scope and rigorous in design. The consensus process identified 29 quality indicators related to the quality of an endoscopy unit among 5 domains that included patient experience, employee experience, efficiency and operations, procedure-related, and safety and infection control. Five priority endoscopy unit quality indicators were identified as the most compelling to measure and track for a high-quality endoscopy unit.

The intent for disseminating this information is to guide endoscopy units in their efforts to assess and improve quality by identifying those areas currently deemed most important to measure. Future efforts should include maturation of the indicators into formal measures and development of appropriate tools to capture these types of quality data. As the capability to record

and track these endoscopy unit quality indicators grows over time we will learn which parameters are most closely linked to important patient outcomes. We will also be able to apply the same principles of quality improvement using these data on endoscopy unit performance that are currently used to improve endoscopic procedure-related outcomes.

This document was reviewed and approved by the governing board of the American Society for Gastrointestinal Endoscopy (ASGE) and was reviewed and endorsed by the Society of Gastroenterology Nurses and Associates (SGNA).

DISCLOSURE

Dr Valori is a director of Quality Solutions for Healthcare LLP and of Anderval Ltd. All other authors disclosed no financial relationships relevant to this publication.

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첨부자료 3

Communication from the ASGE Quality Assurance In Endoscopy Committee

GUIDELINE

ASGE guideline for infection control during GI endoscopy

Prepared by: ASGE QUALITY ASSURANCE IN ENDOSCOPY COMMITTEE

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This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

The Quality Assurance in Endoscopy Committee of the American Society for Gastrointestinal Endoscopy (ASGE) updated and revised this document, which was originally prepared by The Standards of Practice Committee of the ASGE and was published in 2008.[1] *In preparing this guideline, a search of the medical literature was performed by using PubMed, supplemented by accessing the related-articles feature of PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data existed from well-designed prospective trials, emphasis was given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice.*

This guideline is intended to be an educational tool to provide information that may assist endoscopists in delivering care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

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Millions of GI endoscopies are performed annually throughout the United States, and it is reassuring that documented instances of infectious adverse events remain rare.[2] Several recent reports of infections with multidrug-resistant organisms (MDRO) associated with duodenoscope use suggest that prior assumptions regarding endoscopy-related infection rates may be an underestimate, particularly for ERCP. These outbreaks of infection have led to a reassessment of current infection control practices. Endoscopy-related transmission of infections may occur if microorganisms are spread from patient to patient by contaminated equipment or if microorganisms are spread from the gut lumen during endoscopy through the bloodstream to susceptible organs, adjacent tissues, or prostheses. Non-endoscopic transmission of infections within endoscopy units also can occur if microorganisms are transmitted from patients to endoscopy personnel.

The purpose of this document is to disseminate information and promote understanding of endoscopy-related transmission of infection in order to minimize its risk of occurrence. Circumstances in which an endoscopy-related infection might occur are discussed, as are measures to prevent such infection, including endoscope reprocessing and reprocessing failure, general infection control, protection of endoscopy personnel, and the importance of leadership.

OVERVIEW OF ENDOSCOPIC TRANSMISSION OF INFECTION

Over the course of an endoscopic examination, the external surface and internal channels of flexible endoscopes are exposed to body fluids and contaminants. Disinfection of these reusable instruments pose special challenges. Flexible endoscopes are heat labile devices and as such are not suitable for steam sterilization. Therefore, reprocessing is achieved by mechanical and detergent cleaning, followed by high-level disinfection (HLD), rinsing, and drying.

Stringent guidelines for the reprocessing of flexible endoscopes were developed by the ASGE and the Society for Healthcare Epidemiology of America, who convened with representatives from physician, nursing, and infection control organizations, industry leaders, and federal and state agencies. This conference resulted in the 2003 publication of the Multisociety Guideline for Reprocessing of Flexible GI Endoscopes,[3] which was updated in 2011[4] and in 2016.[5] Historically, in the absence of defective equipment, reported cases of transmission of infection have resulted from failure to adhere to these guidelines. Since 2012, multiple U.S. and international medical centers have reported patient-to-patient transmission of MDROs such as carbapenem-resistant *Enterobacteriaceae* (CRE), without identifiable, overt breaches of reprocessing protocol.[6] Transmission of these organisms has been linked to the elevator channel endoscopes (duodenoscopes, linear array EUS scopes) and primarily attributed to persistent contamination of the elevator mechanism, the elevator cable, and the cable channel itself.

Bacterial infections

When clinically significant bacterial infections are transmitted endoscopically, they are often recognized because their incubation periods are often short, and patients usually develop overt clinical symptoms. However, cases of transmission may be missed if the illness is subclinical or if symptoms are attributed to other factors associated with the procedure (issues related to the interventions performed or to sedation) or to other patient-specific conditions or events. Overall, although accurate data on infection transmission rates are difficult to obtain because of the lack of a proper mechanism for reporting and calculation of transmission rates, a summary of the available data, in the context of these reporting limitations, is provided below.

A total of 84 cases of endoscopy-related transmission of *Salmonella* species between patients were reported between 1974 and 1987,[7-15] but none have been reported since that time. Overall, there have been rare reports of endoscopic transmission of *Pseudomonas* species.[16,17] As recently as 2011, 4 patients who underwent upper endoscopy were found to be infected with multidrug-resistant *Pseudomonas*. Several potential causes for the transmission were identified, including insufficient initial cleaning, shortening of immersion and brushing times, insufficient channel flushing, and inadequate drying before storage.[18] In addition to inadequate reprocessing of the endoscope itself, the propensity for organism growth in moisture-rich environments is a common factor in facilitating transmission. In some instances, an unsterilized irrigation water bottle attached to the endoscope was identified as a source of infection.[19,20] A lack of cleaning and drying of the air-water and/or the elevator channels of duodenoscopes also was implicated in some cases of transmission of *Pseudomonas* infection.[21-24] Failure of automated endoscope washer-dryers has been implicated in several cases.[22,25,26] Recently, a strain of *Pseudomonas* with reduced susceptibility to glutaraldehyde was reported.[27]

A few reports of endoscopic transmission of *Helicobacter pylori* were attributed to inadequate reprocessing of endoscopes and biopsy forceps.[28,29] Up to 61% of endoscopes became contaminated after use in patients infected with *H pylori*,[30] but conventional cleaning and disinfection of the instruments are highly effective in eliminating *H pylori*. Before widespread application of standardized reprocessing guidelines, there were isolated reports of endoscopic transmission of other enteric bacteria, including *Klebsiella*,[31] *Enterobacter*,[17] *Serratia*,[32] and *Staphylococcus*.[31]

There have been no reports of transmission of mycobacteria by GI endoscopy. Current reprocessing guidelines were shown to be adequate in eradicating mycobacteria, and to date there are no reports of transmission of mycobacteria by GI endoscopy.[33] Similarly, reprocessing under the current guidelines was shown to inactivate biofilm and the spores of *Clostridium difficile* and other bacteria,[34,35] and no cases of transmission of *C difficile* have been reported.

As mentioned previously, transmission of MDROs, including CRE, via duodenoscopes, has been reported.[24,36-38] Unlike prior outbreaks of endoscope-transmitted infections, no recognized breaches of standard reprocessing protocol have been identified in outbreaks of duodenoscope-associated CRE to date. These transmissions seem to be related to difficult-to-clean or even sealed portions of these specific endoscopes, particularly the areas around the elevator regions of duodenoscopes.

Chronic viral infections

Documentation of transmission of viral infections by endoscopy is more challenging, because these infections have a longer incubation period, and patients may be asymptomatic or minimally symptomatic. Thus, linking transmission of these infections to a previously performed procedure may be difficult. Still, existing data suggest that risk of viral transmission via endoscopy is extremely low to non-existent.

Hepatitis C. There are rare reports of transmission of hepatitis C in situations where lapses in HLD of endoscopes occurred. Older case reports and epidemiologic studies suggested an association between endoscopy and hepatitis C virus (HCV) seropositivity. However, interpretation of these reports is difficult because of a reliance on self-reporting of risk factors for HCV and other inherent biases. In fact, the documented cases of HCV were all related to non-endoscopic transmission rather than direct endoscopy-related transmission. Bronowicki et al[39] documented transmission of hepatitis C from an infected patient to 2 subsequent patients who underwent colonoscopy with the same instrument. Transmission was

originally attributed to 2 breaches in endoscope reprocessing: failure to clean the working channel of the endoscope manually before disinfection and failure to sterilize the biopsy forceps between patients. However, inadequate aseptic techniques practiced at this center also raise the possibility of transmission of the virus via contaminated intravenous tubing, syringes, or multi-dose vials rather than the endoscope itself.[40,41] In another example, a single-center report showed that 8 of 87 (9.2%) HCV-negative patients seroconverted after propofol vials designed for single use were reused on multiple patients undergoing endoscopic procedures.[42]

There is evidence, however, that when currently accepted reprocessing guidelines are followed, transmission of HCV is extremely rare to non-existent. A multicenter prospective cohort study followed 8260 HCV-seronegative patients undergoing endoscopy.[43] All centers reported compliance with internationally accepted guidelines for cleaning and disinfection of endoscopes. All 8260 patients, including 912 patients who underwent an endoscopy with an instrument previously used on HCV carriers, remained seronegative at follow-up testing performed 6 months after their endoscopic procedures. Four seroconversions occurred over the study period in a control group of 38,280 blood donors, which indicated a background seroconversion rate of 0.042 per 1000 patient-years.

Similar results were reported in a prospective cohort study of 859 patients, with a high prevalence of hepatitis C of 71%.[44] Endoscopes were cleaned and disinfected in accordance with guidelines published by the ASGE and the Society of Gastroenterology Nurses and Associates. Of the 149 patients who were seronegative and for whom follow-up serology could be obtained, 4 subsequently developed antibodies to HCV. Two were found to have had HCV RNA in blood samples obtained before an endoscopy, which indicated that they were infected before undergoing endoscopy. Of the remaining 2 patients who developed anti-HCV antibodies after an endoscopy, neither had HCV RNA detected on follow-up testing at 3 and 6 months after the procedure, which suggested false-positive serologic tests. Thus, endoscopy did not result in transmission of hepatitis C in any of these patients, despite the extremely high exposure risk in this cohort.

Hepatitis B. A handful of isolated case reports suggest that transmission of hepatitis B via endoscopy is possible.[45-47] However, transmission of hepatitis B appears to be very rare, even when inadequate cleaning and disinfection occurs, and there are no reported cases of transmission when currently accepted guidelines are followed.

In 5 prospective studies, 120 patients who had undergone endoscopy with an instrument previously used in a patient infected with hepatitis B were followed.[48-52] No hepatitis B virus (HBV)-seronegative patients developed clinical or serologic evidence of hepatitis B over a 6-month follow-up. In 4 additional prospective studies, a total of 722 patients who were HBV seronegative were observed for up to 12 months after an endoscopy.[53-56] The background prevalence rates of hepatitis B surface antigen positivity in these populations were up to 9.6%. In total, only 3 of the 722 patients seroconverted. None of the seroconversions were attributed to the endoscopy because none of these patients had undergone an endoscopy with an instrument previously used on a patient who was infected. In addition, the seroconversion rate was lower than that for a control population not undergoing endoscopy. In a recent prospective cohort study from a center in which ASGE reprocessing guidelines were followed, none of 30 seronegative patients undergoing endoscopy with instruments previously used in patients who were hepatitis B surface antigen–positive subsequently seroconverted.[44] Finally, a recent Canadian study of patients who underwent endoscopy in a unit with identified infection control lapses over a 9-year period confirmed the negligible risk of HBV infection after endoscopy. In this study, 5042 of 6728 (75%) living patients completed bloodborne pathogen testing after endoscopy, and there was no increased risk for infection among those who underwent a procedure within 7 days of a known HBV or HCV case.[57]

Taken together, these data indicate that when currently accepted guidelines for cleaning and disinfection of endoscopes are followed, transmission of hepatitis B after endoscopic procedures does not occur or is very rare.

HIV. There are no reports of transmission of HIV by endoscopy. Manual cleaning of the endoscope with detergent eradicates >99.0% of the virus from the instrument, and subsequent disinfection with glutaraldehyde has been shown to eliminate the virus from endoscopes.[4,58-60]

Miscellaneous microbial transmission

Parasites. A single report documented transmission of *Strongyloides* to 4 patients from a contaminated instrument.[61] There are no other reports of transmission of parasites by endoscopy.

Fungi. There are no documented cases of transmission of fungal infections by GI endoscopy.

Prions. Creutzfeldt-Jacob disease (CJD) is a neurologic disease that is transmitted by proteinaceous agents called prions. GI endoscopy does not result in contact of the endoscope or accessories with prion-infected tissues, and, therefore, there is no theoretical need for any special processing of endoscopes used on patients with CJD.[62] There are no reports of transmission of CJD by endoscopy.

Variant CJD (vCJD) is a related condition caused by the consumption of beef contaminated by the bovine spongiform encephalopathy agent. Approximately 125 cases have been reported worldwide, with a single case reported in the United States. vCJD differs from CJD in that the mutated prion protein can be found in lymphoid tissue throughout the body, including the tonsils and the gut. The mutated prions are resistant to conventional

disinfectants and sterilants. We, therefore, recommend that an endoscopy be avoided, if at all possible, in patients with known vCJD.[63] When an endoscopy must be performed in a patient with known vCJD, we recommend use of an instrument dedicated for patients with vCJD or one that is approaching the end of its life and that can be destroyed after use. Given the absence of any further reported cases of vCJD in the United States, no changes to general reprocessing guidelines are warranted at this time.

Use of endoscopes in animal models

There is a paucity of data regarding risk of transmission of infection via endoscopes used in animal models. The Centers for Disease Control and Prevention (CDC) recommends that "when medical or surgical instruments, especially those invasive instruments that are difficult to clean [eg, endoscopes], are used on animals, these instruments should be reserved for future use only on animals."[64] Some endoscope manufacturers recommend that endoscopes that have been used on animal models should be reprocessed in dedicated automated endoscope reprocessors separate from those used for human endoscopes.

REPROCESSING OF ENDOSCOPES

The single best protection against patient-to-patient transmission of microorganisms by endoscopy is careful compliance with reprocessing guidelines and manufacturers' U.S. Food and Drug Administration (FDA)–approved instructions for use.[5] This section defines and discusses key concepts in endoscope reprocessing. More in-depth discussion is left to the Multisociety Guideline for Reprocessing of Flexible GI Endoscopes 2016 update.[5]

Definitions

Cleaning. This is defined as the physical removal of organic material and/or soil, generally by using water with detergents. This process is designed to remove organisms rather than kill them.

Disinfection. Disinfection eradicates most microorganisms and is commonly performed by using liquid chemical germicides. There are 3 levels of disinfection depending on the degree of microbial elimination involved:[65] (1) High: This includes pasteurization, use of glutaraldehyde or another agent confirmed to achieve HLD. HLD destroys vegetative microorganisms, mycobacteria, fungi, small or nonlipid viruses, and medium or lipid viruses, but not necessarily large numbers of bacterial spores. Chemical germicides registered as "sterilants" may be used for sterilization or for HLD, depending on such factors as dilution, contact time, and frequency of reuse. The specifics of such factors may vary with each product and are included on approved labeling.[65] (2) Intermediate: This uses hospital-grade disinfectant and a U.S. Environmental Protection Agency–approved tuberculocidal cleaner and/or disinfectant and is indicated for any item that touches mucous membrane or skin that is not intact (eg, thermometers). (3) Low: This level of disinfection will inactivate most vegetative bacteria, some fungi, and some viruses, but it does not reliably inactivate resistant microorganisms.

Sterilization

Sterilization eliminates all microbials, including bacterial spores. It is most commonly achieved with heat or ethylene oxide gas.

Spaulding classification

The Spaulding classification categorizes medical devices based on the risk of infection involved with use. The categories of medical devices and their associated levels of disinfection are as follows:

Critical-use items. Critical use items enter sterile tissue or vascular spaces and hence carry significant risk for infection if contaminated. These items include needles, surgical instruments, biopsy forceps, and urinary catheters. Processing for reuse of these items requires sterilization.

Semi-critical–use items. These items, such as endoscopes, come in contact with mucous membranes and do not ordinarily penetrate sterile tissue. Processing for reuse requires HLD.

Noncritical items. These item do not ordinarily touch the patient or touch only intact skin, such as stethoscopes or patient carts. These items may be cleaned by low-level disinfection.

REPROCESSING METHODS

Endoscope reprocessing is a multistage process that includes manual cleaning, HLD (or sterilization in some cases), rinsing, drying, and storage. The ASGE Multisociety Guideline on the Reprocessing of Flexible GI Endoscopes: 2016 update should be referred to for additional information on the multistage process outlined below.[5]

Manual cleaning

The first, and one of the most important, steps in the prevention of transmission of infection by endoscopy, is manual cleaning of the endoscope with detergent solution and brushes.[66,67] Only model-specific cleaning devices, designed for the endoscope model being cleaned, should be used.[5] This should be performed as soon as possible on removal of the endoscope from the patient to prevent drying of material on the surface of the endoscope and within the channels. Manual cleaning minimizes the chances of bacterial biofilm developing within the endoscope channels. The efficacy of cleaning and disinfection is dependent on appropriate training of

personnel and compliance with manufacturers' recommendations. Endoscopes equipped with an elevator channel merit special attention during both manual cleaning and disinfection in order to ensure effective reprocessing of the instrument. This includes both duodenoscopes used in ERCPs and linear-array echoendoscopes used for certain EUS procedures. Manual cleaning of the complex endoscope components, such as elevators, requires optimal lighting and may be facilitated with magnification.[5]

HLD

HLD is the standard of care recommended by governmental agencies and all pertinent professional organizations for the processing of flexible GI endoscopes.[2,4,68,69] HLD is operationally defined by the FDA as a 6-log reduction of *Mycobacteria*[70] and is achievable by using a variety of FDA-approved liquid chemical germicide solutions with a manual process or an automated endoscope reprocessor.[71,72]

Sterilization

Traditionally, sterilization of endoscopes and accessories has been indicated for the rare occasions when they are to be used as critical medical devices, when there is a potential for contamination of an open surgical field.[65] Sterilization can be achieved by using a variety of methods, including ethylene oxide gas treatment, and it can be achieved with appropriately long exposure to liquid chemical germicides.[72,73] Because of the complexity of the instrument channel design, sterilization of flexible endoscopes is difficult to accomplish.[74,75] In addition, endoscope durability and function are potentially compromised with repeated cycles of sterilization.[76] Users report that endoscopes experience a shortened use life because of material degradation issues when processed repeatedly in ethylene oxide.[77] Because of these factors as well as a lack of data for demonstrable benefits to the further reduction in endoscope bacterial spore counts achieved by sterilization instead of HLD, sterilization with ethylene oxide is not recommended over HLD for standard GI endoscopes.[74] However, an FDA-cleared liquid chemical sterilant processing system has been approved to provide sterilization of cleaned, immersible, reusable, and heat-sensitive critical and semicritical medical devices.[77]

Reusable biopsy forceps, snares, sphincterotomes, and other accessories designed to breach the GI mucosal surface all require sterilization.[70] Reusable accessories have the potential for cost savings because they can be used over several procedures; however, repeated sterilization may damage the devices.[78,79]

Although the use of tap water in the irrigation bottle can be safe, with no difference in rates of bacterial cultures compared with sterile water and no associations with clinical infections with use of either tap or sterile water,[80-82] it is recommended that sterile water be used in irrigation bottles when endoscopy is performed in special populations such as liver transplant patients, because of uncertainty regarding the presence of potential water-borne pathogens in tap water.[83]

Duodenoscopes

Because of recent duodenoscope-associated MDRO and CRE infections and known difficulties in adequately cleaning the elevator channel, the FDA has advised consideration of further measures for reprocessing of duodenoscopes including use of double reprocessing cycles, uniform or intermittent surveillance with use of a "culture and hold" policy in which the endoscope is cultured after HLD and withdrawn from use until the results prove negative for persistent contamination, or sterilization by treatment with ethylene oxide gas or a liquid chemical sterilant.[84] If not used uniformly, the aforementioned measures can be used when endoscopes that have been used in patients with known MDRO or CRE infections are reprocessed. A facility's decision to use any of these measures is based on available resources as well as local prevalence and estimated risks of duodenoscope-related transmission of infection. All endoscopy centers should closely evaluate whether they have the expertise, training, and resources to implement 1 or more of the FDA suggested supplemental measures to enhance duodenoscope reprocessing.[5]

Linear array echoendoscopes

There is limited data regarding risk of transmission of CRE via linear array echoendoscopes.[85] Some centers, out of an abundance of caution, have begun processing linear echoendoscopes in a manner similar to that used for duodenoscopes, given that both devices contain elevators.[86] However, other than anectodal reports, there are no published studies of these devices being associated with patient-to-patient transmission of MDROs.

Rinsing, drying, and storage

A critical part of the cleaning and disinfecting process involves proper rinsing and drying of the endoscope channels. During rinsing, large volumes of water are flushed through all channels to accomplish complete evacuation of liquid chemical germicides. Water used for rinsing endoscopes after HLD varies in different institutions and is either potable tap water, bacteria-free water, sterile, or sterile-filtered water.[87,88] However, none of these water types is necessarily free of bacteria, despite their label claims, and the potential for contamination of disinfected endoscopes, and, therefore, for nosocomial infection, still exists.[5,88,89] Microbiologic monitoring of rinse water is not recommended by the CDC, although this remains a controversial issue,[5,90-93] with some countries encouraging the practice.[94] Endoscopes that are sterilized with ethylene oxide must have the channels and materials purged by

prolonged evacuation in a strongly negative pressure or vacuum environment, in order to remove any potential toxic residue from the ethylene oxide gas. In addition, before endoscopes undergo gas sterilization, all moisture must be eliminated from the endoscope channels to avoid the creation of ethylene glycol (antifreeze) during ethylene oxide sterilization.

Thorough drying of the endoscope after rinsing minimizes proliferation of microorganisms during storage, because any residual rinse water that remains in endoscope channels may provide an environment for the microorganisms to colonize and multiply.[5,95] After the endoscope is rinsed with water, a 70% alcohol flush promotes drying and inhibits the growth of organisms in stored instruments.[96] After the instruments are dried, they should be stored in an upright hanging position as per manufacturers' recommendations. There are incomplete data, however, on the importance of commercially sold endoscope storage cabinets, including forced-air irrigation of endoscope channels during storage for keeping endoscopes free of contamination.[97]

There is little information regarding how long endoscopes placed in storage may remain unused before reprocessing is required. Two studies indicate that once endoscopes are appropriately reprocessed, dried, and stored, it is not necessary to reprocess them again if used within 5 to 7 days.[98,99] Other data demonstrate that the use of endoscopes within 21 days of HLD appears to be safe.[5,100] This interval remains poorly defined and requires further study.

Reprocessing failure

Reprocessing failures typically arise because of equipment (automated endoscope reprocessor) or product (HLD) failure or because of human error.[101] Because the efficacy of manual cleaning and HLD is operator-dependent, assignment of staff responsible for endoscope reprocessing, extensive training of the reprocessing personnel, process validation, and quality assurance cannot be overemphasized. Staff competency should be assessed, at the very least, on an annual basis.

Although the risk of transmission of infection through endoscopy is extremely low, institutions have an ethical obligation to inform affected patients in a timely manner when a significant breach in reprocessing is discovered or an endoscope-associated infection is suspected. Prompt notification and counseling may minimize patient anxiety, allow patients to take precautions to minimize the risk of transmitting infection to others, and allow for early serologic testing. This may help distinguish chronic infections from those potentially acquired at the time of endoscopy and to permit earlier initiation of treatment for newly acquired infections.

In the event of reprocessing failure or outbreak caused by a suspected infectious or chemical etiology, environmental sampling should be performed according to standard outbreak investigation protocols.[102,103] Based on these protocols,[102,103] we provide the following recommendations for the management of cases of reprocessing failure: (1) When a breach of the HLD protocol is discovered, it should be reported to the institution's designated infection control personnel, local and/or state public health agencies, the FDA, the CDC, and the manufacturers of the involved equipment (eg, endoscope, disinfectant and/or sterilant, and automated endoscope reprocessor).[102,103] (2) Patients at risk should be notified directly, in a timely manner, of the breach and of the estimated risk of infection. Successful notification or attempts at notification should be documented. (3) Early serologic testing is imperative to distinguish prior infections from those potentially acquired as a result of the breach in the HLD protocol. For cases in which testing is delayed, it may be difficult to exclude the endoscopic procedure as a potential source of the infection. (4) Patients should be advised against donating blood and tissue products and engaging in sexual contact without barrier protection until all serologic testing is complete. (5) Personal counseling should be offered to all patients. The risk of infection should be discussed and placed in context, to minimize patient anxiety. In addition, the possibility that the patient has a prior chronic viral infection should be discussed, along with the role of testing in distinguishing pre-existing from newly acquired infections. (6) Patients should be asked whether they developed new symptoms suggestive of transmission of enteric bacteria or viruses after the endoscopic procedure. Prior vaccination history for hepatitis A and B should be documented. If patients have undergone prior hepatitis B vaccination, post-vaccination titers should be documented if they were measured. An attempt should be made to identify risk factors for hepatitis B, hepatitis C, and HIV. If patients have previously undergone testing for these infections, the results should be documented. (7) Baseline serologic testing for hepatitis B, hepatitis C, and HIV should be performed after reprocessing failure. Patients should be informed about their baseline serology results in a timely manner. (8) Performance of repeat testing, which may include serology and RNA tests, should be considered. The timing and the choice of tests will be influenced by the period of time that has elapsed between patient exposure and initial testing, by the presence or absence of patient symptoms, and by the advice of the institution's infectious diseases specialist. Institutions may consider obtaining follow-up testing at 6 weeks, 3 months, and 6 months after the procedure. In some situations, additional follow-up testing may be advisable at 1 year after exposure.

GENERAL INFECTION CONTROL

Establishing and maintaining general infection control guidelines within an endoscopy unit are essential for creating a high-quality and safe environment for patients and personnel. However, significant practice variation

with regard to infection control has been reported in endoscopy units across the United States. Gaps in both infection control and safety have been noted in over a fifth of U.S. ambulatory endoscopy units, with notable lapses reported for hand hygiene, personal protective equipment, injection safety, medication handling, and equipment processing.[104] Such variation highlights the need for continued and sustained efforts by endoscopy units to ensure that infection control guidelines are maintained and enforced.

Transmission of infection from patient to patient

Two modes of patient-to-patient transmission of infection have been outlined[5] and are classified as non-endoscopic and endoscopic modes of transmission. Both modes have been clearly linked to patients developing infections after an endoscopic procedure and in most cases were the result of a lack of personnel carefully complying with general infection control policies and procedures. Examples of non-endoscopic transmission of infectious organisms include improper handling of intravenous sedation tubing, use of multi-dose vials and/or reuse of needles by endoscopy unit personnel when caring for patients. Both transmission modes put patients at risk of exposure to possible development of an infection and in most cases can be significantly minimized by good infection control practices.

Transmission of infection from patients to endoscopy unit personnel

There are several reports of documented transmission of infection from patients to health care personnel working in endoscopy units. Potential modes of transmission may include needle stick injury,[105,106] blood splashes to the conjunctiva,[107] inhalation of aerosolized microorganisms,[108] and transfer from direct handling of patients. Furthermore, endoscopy unit staff are at higher risk for some types of infections in comparison to other health care workers or the general population. For example, there is a higher prevalence of *H pylori* infection in endoscopy personnel, with an increased prevalence observed with increasing years of practice.[109-112] Appropriate use of personal protective equipment and good hand hygiene should minimize most of these infection risks. Moreover, endoscopy units need to have policies and procedures in place for when personnel have a potential exposure to an infectious organism while at the workplace.[113]

Management of endoscopy unit personnel exposed to infectious agents

There are nearly 600,000 annual percutaneous injuries experienced by U.S. health care workers,[114] with over 5 million health care workers at risk.[115] The risk of developing an infection after such an exposure is low for endoscopy unit personnel with respect to diseases such as HIV,[116] HCV,[117] and HBV.[118] In the event of inadvertent exposure of endoscopy unit personnel to potentially infectious agents, institutional guidelines should be followed. The Occupational Safety and Health Act (OSHA), the U.S. Public Health Service, and the CDC have published recommendations for management after exposure,[119,120] including the following: (1) when prophylaxis is indicated after exposure, (2) the need for consulting experts in the management of such exposures, (3) monitoring for compliance with after-exposure prophylaxis as well as for adverse events and for seroconversion.

Protection of personnel

OSHA 1991, updated in 2001, established guidelines for health care facilities whereby employers are responsible for providing a safe and healthful work environment.[121,122] Areas in which health care personnel encounter blood and other body fluids, such as an endoscopy unit, places them at the greatest risk of being exposed to blood-borne infections. In order to minimize such risks, the OSHA Blood-Borne Pathogens Standard (OSHA ST 29 CFR part 1910.1030) was established and requires employers to evaluate each employee task and provide training to protect employees from exposure to harmful substances. The OSHA Blood-Borne Pathogens Standard established the following requirements for health care facilities: (1) development of an exposure control plan that defines anticipated exposure risks for each employee task and outlines risk-reduction approaches, (2) exposure control plan updated annually, (3) implement the use of universal precautions, (4) identify and use engineering controls (defined as physical changes to the work area or process that effectively minimize a worker's exposure to hazards) to minimize exposure to blood-borne pathogens, (5) identify and ensure the use of work practice controls, (6) provide personal protective equipment for personnel, (7) make available after-exposure evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident, (8) use labels and signs to communicate hazards, (9) provide information and training to workers, (10) maintain worker medical and training records.

Finally, it is further recommended that all of the above requirements be directed by a qualified individual, documented in writing and accessible to all personnel, include policies and procedures to support them, and that there be a process for ongoing assessment of compliance and competency with regard to them.[113]

Standard precautions

Standard precautions are defined as the basic level of infection control precautions, which are to be used, as a minimum, in the care of all patients. The goal of standard precautions is to reduce the risk of transmission of

blood-borne and other pathogens from both recognized and unrecognized sources.

The CDC recommends standard precautions for the care of all patients, regardless of their diagnosis or presumed infection status. Standard precautions apply to (1) blood, (2) all body fluids, secretions, and excretions (except sweat), (3) non-intact skin; and (4) mucous membranes. Because a patient's infectious status is often unknown at the time of an endoscopy, it is prudent to apply standard precautions for blood and body fluids when interacting with all patients. Standard precautions include:[4,123] (1) hand hygiene, (2) personal protective equipment, (3) safe medication administration practices, (4) safe handling of potentially contaminated equipment or surfaces in the patient environment.

Precautions at the institutional level

A variety of measures are needed for optimal infection control among employees, both before and during the period of employment. OSHA mandates that all employees should be immunized against HBV,[124] although the risk of HBV infection to endoscopy unit personnel is small.[125] Other agencies and medical societies have gone further and recommended that health care personnel should have documented immunity or be immunized against a number of other vaccine-preventable diseases. Such vaccinations include annual influenza immunizations, measles/mumps/rubella, varicella (if the individual has not had chickenpox in the past), tetanus/diphtheria/pertussis, and meningococcus.[123,124] Additionally, a majority of states have immunization laws for health care workers with which institutions must comply. Last, an effective and readily accessible employee health service may play a critical role in the management of after-exposure prophylaxis.[125]

Precautions in the endoscopy unit

A number of essential precautions should be observed in the endoscopy unit in order to minimize infectious risks to both personnel and patients. Hands should be washed before and after each patient interaction, whether or not gloves are worn. The use of soap and water is required when hands are visibly soiled or an employee has an encounter with a patient with a suspected and/or known infectious cause of diarrhea. In all other cases, alcohol-based agents are acceptable.[102,126] In endoscopy units, the prevention of *C difficile* transmission should be considered when endoscopy is performed on patients with diarrhea or known *C difficile* infection. Handwashing with soap and water should be undertaken for mechanical removal of spores from employee hands. Similarly, the use of gloves by health care workers during this type of patient encounter is required, because it has been shown to decrease the incidence of *C difficile*-associated diarrhea and the point prevalence of asymptomatic *C difficile* carriage in inpatients.[127]

Patients with respiratory diseases that can be spread via an airborne route (eg, tuberculosis) may place endoscopy unit personnel at an increased risk of contracting the disease. Special precautions should be undertaken for patients who fall into this category and require endoscopy. Endoscopic procedures should be performed in a negative-pressure room, such that the direction of the air flow is from the outside adjacent space into the procedure room. Additionally, the use of personal respiratory protection is indicated for persons entering these rooms and for staff who lack immunity to airborne viral diseases (eg, measles, varicella zoster virus, influenza). Finally, the procedure room should be cleaned per standard protocol as described below.[128]

Maintenance of a clean and sanitary environment for patients and personnel must be ensured. After the endoscopic procedure, exposed surfaces should be thoroughly cleaned of visible contaminants and then disinfected with an Environmental Protection Agency–registered hospital disinfectant.[65,129] Rigorous cleaning of the endoscopy unit with a bleach-containing disinfectant for environmental disinfection is needed when patients with, or suspected of having, *C difficile* or norovirus undergo an endoscopic procedure. Also, isolation precautions that are otherwise indicated in patients who are potentially infected should be maintained when patients are transported to endoscopy units. For some patients, convenience or isolation requirements may require performance of an endoscopy at the bedside, rather than in the endoscopy unit. Finally, each endoscopy unit should have a plan in place for the cleaning and disinfecting of the procedural space at the end of the day.[4]

Safe medication administration practices and the safe use of needles in the endoscopy unit must be followed. Needles should be discarded in sharps containers without recapping to avoid inadvertent needle sticks. Endoscopy units and institutions should adopt needleless systems for administration of parenteral drugs whenever feasible. Clear and detailed recommendations for safe injection practices have been outlined in several recent guidelines.[102,113,130,131] In particular, it should be emphasized that single-dose vials should be used, all medications should be labeled, reuse of syringes to enter a medication vial or solution should be prohibited, and the same syringe should not be used to administer medications to multiple patients.

It should be noted that infection control and the architectural layout of the endoscopy unit are intertwined. Endoscopy unit infection control policies should address procedure room work areas, reprocessing rooms, the separation of soiled and clean tasks and the flow of soiled and clean equipment through the unit, and the handling of specimens, tissues, soiled linens, and contaminated wastes should conform to both state and national regulatory guidelines.[132] The physical design of the endoscopy unit and rooms significantly influences whether these infection control issues can be adequately and efficiently addressed.[133,134]

Personal protective equipment

Personal protective equipment is defined as specialized clothing or equipment that does not permit blood or other potentially infectious material to pass through clothes or into skin, eyes, or mouth when worn by an employee for protection against a hazard. OSHA requires that employers provide all generally available protective attire, that they instruct employees in their use, and that they ensure their use by the employee.[132] The ASGE Technology Assessment Committee and ASGE Ensuring Safety in the Gastrointestinal Endoscopy Unit Task Force provided a thorough discussion of personal protective equipment, their rationale, and the applicable regulations about their use.[113,135] Although there are no endoscopy-specific mandates, institution-wide policies must define appropriate protective wear for the reasonably anticipated exposure of a given task and in most cases is dictated by whether personnel are at risk for a low or high risk exposure.[133] Gowns, gloves, masks, and eyewear should be worn in all settings in which contact with bloodborne pathogens or other potentially infectious materials might be anticipated. Of note, personal protective equipment should never be reused and must be removed when the wearer leaves a procedure room.

Terminal cleaning

The endoscopy unit should have a written plan addressing the terminal cleaning of all procedure rooms, including methods and chemical agents for cleaning and disinfecting the procedure space at the end of the scheduled procedure day.[113] Terminal cleaning should be performed after known cases of *C difficile* and potentially other organisms as determined by the local institution.

The terminal cleaning process should include cleaning of all surfaces in the procedure room sufficient to remove all soil and biofilm, followed by proper disinfection. This requires use of 2 distinct agents because chemical disinfectants are not effective at cleaning, and cleaning agents are not effective at disinfecting surfaces. Agents for terminal cleaning should have efficacy in spore removal, which may differ from requirements for agents used in sterile operating rooms.

Before the first procedure of the day, staff should verify that all procedure and recovery areas have been properly cleansed. A training and competency assessment program should be in place for staff who are involved in terminal cleaning to ensure proper and safe handling and use of the chemicals.

LEADERSHIP

Although it is essential for all staff to participate in enforcing and maintaining infection control, it is critical to have a leadership and governance structure in place to develop policies and procedures around infection control as well as to lead and potentially direct quality improvement projects in this area. It is necessary for endoscopy units to have defined and inclusive leadership, with a focus on meeting and satisfying regulatory requirements with regard to safety and infection control.[136] This leadership team should be diverse and include both physician and nursing representation. Furthermore, at a minimum, endoscopy units are required to have a qualified person who directs infection prevention plans.[137] The role of this individual is to serve as an infection control champion and to implement infection control best practices and technology, lead change management among staff, and be responsible for developing educational materials on infection control practices for staff. Evidence suggests that having a defined and engaged infection control champion in an organization can lead to significant and sustained improvements in the area of infection control.[138,139]

TABLE 1.

The Centers for Disease Control and Prevention system for categorizing recommendations is as follows:
Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.
Category IC. Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an IC recommendation implies the absence of state regulations.
Category II. Recommended for implementation and supported by suggestive clinical or epidemiologic studies or theoretical rationale.
No recommendation. Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.

SUMMARY

1. Transmission of infection as a result of GI endoscopes is extremely rare, and most reported cases are attributable to lapses in currently accepted endoscope reprocessing protocols or to defective equipment.
2. Endoscopes should undergo HLD as recommended by governmental agencies and all pertinent professional organizations for the reprocessing of GI endoscopes (Table 1, Category IB and IC).
3. Attention should be focused on preventing transmission of highly resistant organisms by duodenoscopes, in particular, on ensuring cleaning and HLD of the elevator mechanism and elevator wire channel (Category IB).
4. Extensive training of staff involved in endoscope reprocessing is mandatory for quality assurance and for effective infection control, and documentation of this training is required (Category IC).
5. The efficacy of manual cleaning and HLD is operator dependent, thus assignment of personnel responsible for endoscope reprocessing, extensive training of

reprocessing personnel, process validation, and quality assurance is vital, and staff competency should be assessed at the very least on an annual basis (Category IB and IC).
6. In the event of reprocessing failure, the patient, the institution's designated infection control personnel, local and/or state public health agencies, the FDA, the CDC, and the manufacturers of the involved equipment should be notified immediately (Category IC).
7. General infection control principles should be complied with in the endoscopy unit (Category IA and IC).
8. Use of standard precautions reduces the transmission of infection from patients to endoscopy personnel (Category IA and IC).
9. Endoscopy units must have a qualified individual who directs their infection prevention plans (Category II).

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; CDC, Centers for Disease Control and Prevention; CJD, Creutzfeldt-Jacob disease; CRE, carbapenem-resistant Enterobacteriaceae; FDA, U.S. Food and Drug Administration; HBV, hepatitis B virus; HCV, hepatitis C virus; HLD, high-level disinfection; MDRO, multidrug-resistant organism; OSHA, Occupational Safety and Health Act; vCJD, variant Creutzfeldt-Jacob disease.

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첨부자료 4

The European Society of Gastrointestinal Endoscopy Quality Improvement Initiative: developing performance measures

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The European Society of Gastrointestinal Endoscopy (ESGE) and United European Gastroenterology (UEG) have a vision to create a thriving community of endoscopy services across Europe, collaborating with each other to provide high quality, safe, accurate, patient-centered and accessible endoscopic care. Whilst the boundaries of what can be achieved by advanced endoscopy are continually expanding, we believe that one of the most fundamental steps to achieving our goal is to raise the quality of everyday endoscopy. The development of robust, consensus- and evidence-based key performance measures is the first step in this vision.

ESGE and UEG have identified quality of endoscopy as a major priority. This paper explains the rationale behind the ESGE Quality Improvement Initiative and describes the processes that were followed. We recommend that all units develop mechanisms for audit and feedback of endoscopist and service performance using the ESGE performance measures that will be published in future issues of this journal over the next year. We urge all endoscopists and endoscopy services to prioritize quality and to ensure that these performance measures are implemented and monitored at a local level, so that we can provide the highest possible care for our patients.

Abbreviations

ADR	adenoma resection rate
AGREE	Appraisal of Guidelines for Research and Evaluation
AMSTAR	Assessing the Methodological Quality of Systematic Reviews
ASGE	American Society for Gastrointestinal Endoscopy
CARE	Complete Adenoma Resection [study]
CIR	cecal intubation rate
CRC	colorectal cancer
EOI	expression of interest
ERCP	endoscopic retrograde cholangiopancreatography
ESGE	European Society of Gastrointestinal Endoscopy
GI	gastrointestinal
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ISFU	Importance, Scientific acceptability, Feasibility, and Usability
NQMC	National Quality Measures Clearinghouse
PCCRC	post-colonoscopy colorectal cancer
PICOS	population/patient, intervention, comparison, outcome, study design
QUADAS	Quality Assessment Tool for Diagnostic Accuracy Studies
QIC	Quality Improvement Committee
SIGN	Scottish Intercollegiate Guidelines Network
UEG	United European Gastroenterology

The importance of quality

Tens of millions of people undergo endoscopic procedures every year in Europe. Endoscopy is the pivotal investigation in the diagnosis of gastrointestinal pathology and a powerful tool in its management. High quality endoscopy delivers better health outcomes and a better patient experience [1]. yet there is clinically significant variation in the quality of endoscopy currently delivered in endoscopy units [2–6].

An example of this is post-colonoscopy colorectal cancer (PCCRC). It is known that the majority of PCCRCs arise from missed lesions (premalignant polyps or cancers]. or incomplete polypectomy [7,8]. Back-to-back colonoscopy studies show that 22% of all adenomas are missed [9–14], and that there is a three- to sixfold variation in adenoma detection rates between endoscopists [15,16].

Even when polyps are found, removal may be incomplete: the Complete Adenoma REsection (CARE) study concluded that 10% of nonpedunculated polyps of 5–20 mm and 23% of nonpedunculated polyps of 15–20 mm were incompletely resected [17]. Furthermore, low cecal intubation rates and poor bowel preparation regimens may explain the relative failure of colonoscopy to protect against proximal colorectal cancer that was found in many studies [18–25]. This results in clinically important differences in quality of care and patient outcomes: a recent study in the UK demonstrated a more than fourfold variation in PCCRC rates between hospitals [26].

In the upper GI tract, gastric cancers and precursor lesions are frequently missed: in one series, 7.2% of patients with gastric cancer did not have the lesion detected at endoscopy performed in the preceding 1 year. Of these cases, almost three quarters were felt to be due to endoscopist error [27]. Equally, in ERCP, which is one of the most complex and highest risk procedures performed regularly in endoscopy practice, there is evidence of wide variation in both completion and complication rates [28–35].

Performance measures

Providers and users of services can only know whether their service is delivering good quality care if it is measured. *Performance measures* are measurements that are used to assess the performance of a service or aspect of a service; other terms used for these include *quality measures*, *quality indicators*, *key performance indicators*, or *clinical quality measures*. Evidence-based performance measures provide endoscopists and endoscopy units, both often working in relative isolation, with a framework and benchmark against which they can assess their service.

Knowledge of the significant variation in quality between endoscopists does not improve quality per se, but setting minimum and target standards within these measures incentivizes improvement: when clinicians and services see their own performance data, they act to improve them. Open publication of performance measures also permit users of the service to assess quality for themselves, thus making better informed choices and further incentivizing improvements in healthcare. However, although open publication has potential benefits, it can cause unintended damage if handled poorly, for example if data are open to misinterpretation or inappropriate comparison. Thus it is important to consider both the benefits and risks of open publication for each case.

The provision of high quality endoscopic care is complex, involving myriad people, processes, and equipment. Healthcare professionals work hard to deliver this service, yet failure of any aspect may result in suboptimal care and poor health outcomes. Performance measures help a service to identify, appraise, and monitor the key steps in the process and the key outcomes, showing where systems are suboptimal and whether the service is providing high quality patient-centered healthcare.

Carefully constructed performance measures should allow providers to identify and address specific deficits in their service, resulting in better patient outcomes. Good performance measures should therefore correlate with an important health outcome. These measures should be evidence-based, clear, objective, reproducible, and realistic. They should also be practical to measure and meaningful for their target audience (for example endoscopists, patients, or healthcare providers). In an ideal construct, there should be a small number of carefully selected performance measures assessing all important aspects of the service (domains). Each measure assesses performance from a specific angle. Together they provide a holistic snapshot of the quality of the service. Some performance measures may relate to broad procedures (for example, cecal intubation rate), whereas others may relate to specific steps in a specific procedure (for example the optimal biopsy strategy for surveillance of Barrett's esophagus).

Performance measures can be used to measure the quality of organizational structure, healthcare processes, or clinical outcomes. They can be applied in the pre-, intra- or post-procedural time periods.

- **Structural measures** reflect the conditions in which providers care for patients, in other words they reflect aspects of healthcare infrastructure. These measures can provide information about procedural volumes performed by a provider, staffing levels or, for example, whether a provider has adopted an electronic endoscopy reporting system.
- **Process measures** show whether actions proven to benefit patients are being completed. An example would be the percentage of patients requiring pre-procedure antibiotics who receive the correct antibiotic at the correct time.
- **Outcomes measures** analyze the actual results of care. These are generally the most important measures. An example would be the percentage of patients readmitted to hospital for a complication within 30 days of the endoscopic procedure.

Performance measures describe what to measure. However, it is usually desirable to take this further, identifying a minimum standard and a target standard within the measure. For example, it might be decided that cecal intubation rate is an important performance measure of colonoscopy; within this, a minimum standard might be set at 90% or 95%, with a target standard of 97%. Whereas performance measures will remain relatively static over time, the standards within such measures will be more dynamic, changing over time as techniques and technology improve. Moreover, the standards may vary according to procedure: for example, the minimum standard for adenoma detection rate will be higher for diagnostic colonoscopy performed because of fecal occult blood findings compared with colonoscopy prompted by symptoms. Occasionally no clear minimum standard currently exists for a performance measure (for example, patient comfort), yet its assessment may still be considered important. These are sometimes described as "auditable outcomes," and it is hoped that in time, further research will help determine appropriate standards. Owing to small sample size, rates for rare events, such as missed cancers, may be best examined at endoscopy unit level rather than endoscopist level, whilst a qualitative review of each case is also performed (root cause analysis).

The terminology used in measuring quality can be confusing. A summary of terminology is presented in **Table 1**.

Table 1 Terminology used in measuring quality.

Term	Description/definition	Example
Domain	An area of clinical practice	Completeness of procedure, identification of pathology, management of pathology, complications, patient satisfaction
Performance measure	A measure that helps assess performance within a domain. Other terms used for this include *quality measure, quality indicator, key performance indicator*, or *clinical quality measure*. Can look at structure, process, or outcome.	Cecal intubation rate (CIR)
Minimum standard	A minimum defined level of performance within a performance measure	Minimum CIR standard is ≥ 90 %
Target standard	A desirable/aspirational level of performance within a performance measure	Target CIR standard is ≥ 95 %

The ESGE Quality Improvement Initiative

The ESGE Quality Improvement Committee (QIC) was instigated in 2013. Its aims are:

- To improve the global quality of endoscopy and the delivery of patient-centered endoscopy services
- To promote a unifying theme of quality of endoscopy within ESGE activities, achieved by collaborating with other ESGE committees and working groups and underpinned by a clear quality improvement framework
- To assist all endoscopy units and endoscopists in achieving these standards.

QIC committee membership comprises the QIC chairperson (M.R.), ESGE president and president-elect, chairs of the other three ESGE committees (guidelines, education and research) and chairs of QIC working groups.

A QIC strategy was developed to aid fulfilment of ESGE QIC aims. Quality improvement is a dynamic process and as such the strategy details will evolve over time, although the broad quality remit will not. An initial key objective was to help improve the quality of gastrointestinal endoscopy by producing a framework of performance measures for endoscopy, including quality of independent endoscopists and quality of endoscopy services (covering all aspects of the service including equipment, decontamination, waiting times, and patient experience), by developing robust, evidence-based performance measures. The aim of this was to set a minimum standard for individual endoscopists and for the endoscopy service, and to permit endoscopy units to measure their services against this patient-centered framework.

It was determined that such performance measures should be constructed using a rigorous evidence-based consensus process, incorporating a wide variety of stakeholders, including patients, from as wide a geographical area as possible. The aim was to delineate the core domains of a quality endoscopy service, to identify performance measures within each domain, and precisely to define and describe a small number of key performance measures covering each domain.

As the project fulfilled a key aim of the UEG Strategic Plan 2015 – 2018, ESGE approached UEG regarding potential collaboration and UEG agreed to this collaboration. Both ESGE and UEG co-funded the project and provided additional project governance.

The QIC committee created four working groups related to different areas of the gastrointestinal (GI) tract: upper GI, lower GI, pancreatobiliary, and small-bowel. A fifth "Endoscopy Service" working group was also created. An open call for expressions of interest (EOI) in participation was launched by ESGE, by emailing all individual members and all ESGE-affiliated endoscopy societies and by placing an article in the ESGE newsletter. A total of 90 EOIs were received from over 30 nations. The QIC committee nominated, approached, and appointed working group chairs and a meeting with these chairs was held to discuss the project in detail. Utilizing the list of EOIs, each working group chair established their working group membership, aiming to ensure as wide a geographical spread as possible, with between 10 and 20 members per GI tract group. Because of the nature of the Endoscopy Service group with regards to varying practice between nations, membership of this working group was deliberately larger and each ESGE-affiliated national endoscopy society was asked to nominate an individual to participate in the group, which comprised 34 members. No individual was permitted to be in more than one group. The American Society for Gastrointestinal Endoscopy (ASGE) was approached regarding collaborative involvement and agreed to provide input specifically into the small-bowel working group, along with overall comment or endorsement of the project output as appropriate.

The QIC committee contracted an expert team of methodologists to provide methodological support and to conduct the detailed literature searches (Literature Group). The Literature Group leader (C.S.) was co-opted onto the QIC committee for the duration of the project. To facilitate the program, a bespoke web-based platform was commissioned (ECD Solutions, USA). Within this platform, modules were created corresponding to the steps in the development process. All working group members had access to these modules, permitting both open and anonymized discussion around each aspect of the performance measure development. An expert in guideline methodology with significant prior experience of working with similar web-based platforms (C. Bennett) was commissioned to facilitate the integration of the information technology component.

Performance measures project process

A multistep process was developed by the QIC committee (**Table 2**). The Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool was used to structure the guideline development process [36], incorporating best practice from both the Scottish Intercollegiate Guidelines Network (SIGN) development processes and the National Quality Measures Clearinghouse (NQMC) of the United States of America. To ensure working group members had an understanding of guideline development methodology, all completed the SIGN online critical appraisal course (http://www.sign.ac.uk/methodology/tutorials.html; with permission).

A preliminary meeting for all working group members was held at the UEG Week conference in Vienna, October 2014. The project was explained in detail and each working group proposed potential domains for endoscopy. After open discussion, a draft single set of domains, unified across all the four GI tract areas, was constructed and voted on using a modified Delphi consensus pro-

Table 2 Performance measures project: process steps.

Establishment of QIC and project working groups
Declaration of conflicts of interest – all working group members
Complete SIGN online critical appraisal course – all working group members
Define the domains across all four GI fields (upper GI, small-bowel, pancreatobiliary, lower GI) and separately for Endoscopy Service (agreed by modified Delphi consensus process across all working groups)
Create PICOs, listing all key outcomes
Conduct literature search and construct evidence table
Create long-list of performance measures for each domain within each working group
Use ISFU checklist (**Table 5**) for each potential performance measure. Discard inferior performance measures, and where no performance measure exists within a domain, construct appropriate performance measure by modified Delphi consensus process
Determine final performance measures – modified Delphi consensus process
Develop descriptive framework for each performance measure (**Table 6**). Review, tabulate and GRADE evidence for minimum/target standards within each performance measure
Review and harmonization of performance measures across all five working groups
Highlight areas for future research based on gaps in evidence identified during this process
Identify training/education needs
Review by ESGE, UEG, national societies, and patient groups for comment and consensus
Final amendments – modified Delphi process including ESGE QIC committee

QIC, Quality Improvement Committee; SIGN, Scottish Intercollegiate Guidelines Network; GI, gastrointestinal; PICOS, population/patient, intervention, comparison, outcome, study design; ISFU, Importance, Scientific acceptability, Feasibility, and Usability; GRADE, Grading of Recommendations Assessment, Development and Evaluation; ESGE, European Society of Gastrointestinal Endoscopy : UEG, United European Gastroenterology.

Table 3 Modified Delphi consensus process.

Consensus voting was conducted through the website. Consensus was reached using a modified Delphi technique. Each working group member anonymously scored their level of agreement with draft measures using a 1 to 5 scale: 1 = Strongly agree, 2 = Agree, 3 = Neither agree nor disagree, 4 = Disagree, 5 = Strongly disagree.
Space was provided to include comments and additional references that were felt to require consideration. Commenting was mandatory for undecided or disagree votes.
At least 80 % agreement (scores of 1 or 2) was required for consensus to be reached. Where consensus was not reached, measures were reviewed in light of comments made and any additional evidence identified, and were adjusted if required. Further voting rounds then took place for these measures.
If 80 % agreement was not reached after a maximum of three rounds of voting, consensus was considered reached if > 50 % of participants voted in favor and < 20 % voted against the measure, in accordance with the GRADE process [37]. Failure to meet this criterion resulted in the measure being discarded.

cess, as described in **Table 3** [38]. If consensus was not reached initially, further discussion and voting was performed to re-evaluate and modify proposed domains until consensus was reached. The agreed domains for the GI tract working groups included completeness of procedure, identification of pathology, management of pathology, complications, procedure numbers, and patient experience.

Each working group developed an exhaustive list of potential areas for literature review, using the PICOS (Population/Patient, Intervention, Comparison, Outcome, Study design) process [39–41]. The questions were focused on the assessment of the relationship between specific indicators and procedure outcomes (e.g. completion rate) or patient outcomes (e.g. interval cancer rate, change in clinical management). PICOS were reviewed by the Literature Group and revisions made until a final precisely defined list was reached. The PICOS components of each prioritized question were used by the Literature Group to define specific keywords for the comprehensive bibliographic searches. If more than one comparison was deemed to be relevant, the results of each comparison were reported.

Searches were performed on the Cochrane Central Register of Controlled Trials (CENTRAL), Medline and Embase, from 1 January 2000 to 28 February 2015, using MESH terms and free-text words, without language restriction. In the first instance systematic reviews were searched. If updated systematic reviews addressing the PICOS questions were retrieved, the search for primary studies was limited to those studies published after the last search date of the most recently published systematic review. If no systematic reviews were found, a search of primary studies since 2000 was performed. In order to avoid repetition or double counting of primary studies, where a literature search retrieved many systematic reviews addressing the same PICOS question, only the best systematic review, based on the evaluation of their methodological quality, update of the bibliographic search, level of overlapping, and quality of evidence of included primary studies, was considered for data extraction.

A hierarchy of the study designs to be considered for each type of question (e.g. on effectiveness, diagnostic accuracy, acceptability, and compliance) was produced by the epidemiologists of the Literature Group. For effectiveness questions, randomized controlled trials were considered as the best source of evidence and were searched in the first instance. For diagnostic accuracy questions, cross-sectional studies with verification by reference standard were considered as the best source of evidence.

The risk of bias of included studies was assessed using the following validated checklists:

- systematic review: AMSTAR (Assessing the Methodological Quality of Systematic Reviews) checklist [42]
- randomized controlled trials: The Cochrane Collaboration's tool for assessing risk of bias in randomized trials [43]
- cohort studies, case-control studies and cross-sectional surveys: Newcastle-Ottawa Scale [44]
- diagnostic accuracy studies: QUADAS 2 (Quality Assessment Tool for Diagnostic Accuracy Studies 2) checklist [45]
- interrupted time series analysis: criteria suggested by the Cochrane Effective Practice and Organisation of Care Review Group [46].

The draft results of the bibliographic search and of the selection process produced by the Literature Group were reviewed by the clinical experts of the working groups, to determine whether the inclusion of additional evidence or the exclusion of nonrelevant papers was required. Once necessary revisions were made, for each question or group of questions pertaining to the same topic, the Literature Group provided an evidence table with the main characteristics of each included study (study design, objective of the study, comparisons, participant characteristics, outcome measures, results, risk of bias). They also provided a summary document with a description of the search strategy used for each database, the overall number of titles retrieved, and the

number of potentially relevant studies acquired in full text; the number of studies finally included was given, as well as a synthesis of their characteristics and risk of bias, and of their results, overall conclusions, and quality of evidence.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool was used to evaluate both the quality of evidence and the strength of recommendations made (Table 4) [48, 49]. The GRADE system specifically separates the quality of evidence from the strength of a recommendation: whilst the strength of recommendation may often reflect the evidence base, the GRADE system allows for occasions where this is not the case, for example where there appears to be good reason to make a recommendation in spite of an absence of high quality scientific evidence such as a large randomized controlled trial.

Once the literature review was completed, initial draft evidence statements with comprehensive supporting documentation were uploaded onto a customized web platform, for all working group members to review and comment in a modified Delphi process (see Table 3), to allow modification and to identify additional references. Where necessary, further literature reviews were undertaken and further revisions made in subsequent voting rounds.

From the final evidence construct, the working group chairs identified draft performance measures, aiming for a small number of key measures per domain. Where no measure had been identified within a domain, the working group was permitted to construct one by consensus if deemed clinically appropriate. Once the key performance measures had been identified, each measure was evaluated using the ISFU (Importance, Scientific acceptability, Feasibility, and Usability) framework described by the National Quality Measures Clearinghouse (Table 5) [50]. Measures which did not meet the criteria were discarded. The modified Delphi process was then used to reach consensus on these performance measures.

A detailed descriptive framework was then constructed for each measure meeting the ISFU criteria, as described in Table 6 [51]. Quality standards (minimum and target) were identified within each performance measure. Additional literature searches were performed where necessary. Where no evidence-based standard was identified, the working group was permitted either to agree on a suitable standard by consensus, or to state "no current standard defined."

Along with the final list of precisely defined key performance measures, the working groups compiled a longer list of other performance measures that had been identified during the development process, a list of areas with weak evidence base for priority research, and a list of training/educational needs. The final draft was then reviewed by the ESGE QIC Committee and the ESGE Governing Board. Finally, review and approval was obtained from ESGE-affiliated national societies, UEG, ASGE, and patient groups.

Table 4 An overview of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system [47].

GRADE: Strength of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: Any estimate of effect is very uncertain
GRADE: Strength of recommendation
Recommendations can be categorized as either **Strong** or **Weak**. Recommendations involve a trade-off between benefits and harms. Those making a recommendation should consider four main factors: – The trade-offs, taking into account the estimated size of the effect for the main outcomes, the confidence limits around those estimates, and the relative value placed on each outcome – The quality of the evidence – Translation of the evidence into practice in a specific setting, taking into consideration important factors that could be expected to modify the size of the expected effects, such as proximity to a hospital or availability of necessary expertise – Uncertainty about baseline risk for the population of interest. If there is uncertainty about translating the evidence into practice in a specific setting, or uncertainty about baseline risk, this may lower our confidence in a recommendation.

The ESGE quality improvement vision

ESGE and UEG have a vision to create a thriving community of endoscopy services across Europe, collaborating with each other to provide high quality, safe, accurate, patient-centered, and accessible endoscopic care. Whilst the boundaries of what can be achieved in advanced endoscopy are continually expanding, we believe that one of the most fundamental steps to achieving our goal is to raise the quality of everyday endoscopy. The development of robust, consensus- and evidence-based key performance measures is the first step in this vision.

Implementing performance measures, along with additional measures such as structured training programs, can result in significant improvement in endoscopy quality. In the UK for example, a decade of quality improvement initiatives resulted in cecal intubation rate improving from 76.9% to 92.3% [52].

Having a performance measure does not result in improved health outcomes per se: in order to improve quality, it is essential to measure local performance regularly against this benchmark. Services and individuals are unlikely to improve unless they are aware of their performance and how it compares with benchmark performance measures. Measuring allows the identification of potential underperformance, which provides an opportunity for discussion and support for the endoscopist. In addition, the simple act of monitoring a service will improve performance (the "Hawthorne effect"): it is powerful, essentially free, and results in improved quality of patient care.

The standardization of performance measure definitions and measurement methodology is crucial to permit comparative assessment. Quality improvement requires political will. At a local level, it requires support from hospital management. Whilst not essential, the best examples of quality improvement in endoscopy have also had commitment from, indeed have often been led by, regional or national authorities and we call upon such organizations to share responsibility for and to facilitate this program. The implementation of appropriate information technology infrastructure, based around electronic endoscopy reporting systems, is an important step in allowing timely data collection and automated, standardized performance measure reporting.

A strong case can be made for setting a minimum number of procedures per endoscopist per year. Firstly, a large sample size in-

Table 5 Importance, Scientific acceptability, Feasibility, and Usability (ISFU) system, customized and adapted to our working group needs.

Importance to measure and report	Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high priority aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.	**1a. Evidence base** The measure focus is evidence-based: – **Health outcome:** a rationale supports the relationship of the health outcome to processes or structures of care. – A systematic assessment and grading of the quantity, quality, and consistency of the evidence that the measured **structure, process or intermediate clinical outcome** leads to a desired health outcome.**1b. Performance gap** Demonstration of quality problems and opportunity for improvement **1c. High priority** A high priority aspect of healthcare.
Scientific acceptability of measure properties	Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.	**2a. Reliability** The measure is well defined and precisely specified so it can be implemented consistently and allows for comparability. **2b. Validity** The measure specifications are consistent with the evidence. Target population and exclusions are supported by the evidence. Validity testing demonstrates that the measure correctly reflects the quality of care provided, adequately identifying differences in quality. Where an evidence-based risk-adjustment strategy is specified, it has demonstrated adequate discrimination and calibration. Analysis of computed measure scores demonstrates that scoring allows for identification of statistically significant and practically/clinically meaningful differences in performance. If multiple data sources/methods are specified, there is demonstration they produce comparable results. For measures susceptible to missing data, analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that results are not biased due to it and how the specified handling of missing data minimizes bias. **2c. Disparities** If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results.
Feasibility	Extent to which the specifications, including measure logic, required data that are readily available or could be captured without undue burden and can be implemented for performance measurement.	**3a.** For clinical measures, the required data elements are routinely generated and used **3b.** The required data elements are available in electronic sources, or a credible path to electronic collection is specified. **3c.** Demonstration that the data collection strategy can be implemented
Usability and use	Extent to which potential audiences (e.g., consumers, purchasers, providers, policymakers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high quality, efficient healthcare for individuals or populations.	A credible rationale describes how the performance results could be used to further the goal of high quality, efficient healthcare for individuals or populations.
Comparison to related or competing measures	If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.	**Consider multiple measures in a domain if:** The measure is harmonized with related measures or multiple measures are justified. **Consider replacing existing measure if:** The measure is superior to existing measures

creases the accuracy of the performance measurement (i.e., it reduces the probability that apparent underperformance is a chance event). Secondly, there is evidence that endoscopy proficiency increases with increasing number of procedures performed, and that endoscopy complications are more common with endoscopists who perform fewer procedures per year [1]; this is also well described in many other clinical areas such as surgery [53]. A trend towards fewer endoscopists each performing more procedures may be appropriate, and setting a minimum number of procedures per year for endoscopists may be one strategy to improve quality.

It is important that we help endoscopists with lower levels of performance to improve. Quality assurance should be about improvement, not punishment. One of the biggest gains in endoscopy quality improvement would be to raise the standards of the lower performers to above minimum quality standard thresholds. Various organizations have developed structured processes for the management of underperforming endoscopists, and experience shows that when handled sensitively but robustly, most endoscopists embrace such support. However, there may at times be barriers to the uptake of endoscopy quality improvement by individuals and even services, ranging from complacen-

Performance measure	[name]
Description	Provide a concise summary statement of performance measure
Domain	[domain name]
Category	Structure/Process/Outcome
Rationale	Explain the importance of the measure
Evidence for performance measure	Use GRADE system for **evidence base** and for **strength of recommendation**
Details	Clearly describe: Target population (denominator) Identification of those from the target population who achieved the specific measure focus (numerator, target condition, event, outcome) Measurement time window Exclusions Risk adjustment/stratification Definitions Data source and feasibility Consider handling of missing data Specifications for composite performance measures include: component measure specifications (unless individually endorsed); aggregation and weighting rules; handling of missing data; standardizing scales across component measures; required sample sizes
Scoring	Describe how the performance measure is calculated (e.g. mean/median, count, ratio, rate/proportion) Indicate if stratification/case mix adjustment or weighting required Frequency of calculation. Describe level of analysis (e.g. individual endoscopist – cecal intubation rate; or service level – bowel preparation quality)
Minimum/target standards	Describe minimum/target standards State "no current standard defined" where none exists Describe how score should be interpreted relative to the minimum/target standard Describe whether the standard includes any tolerance for any factors Describe action that should be taken when performance does not reach minimum standard

Table 6 Customized and adapted descriptive framework for each final performance measure.

cy ("I'm fine and don't need to measure") to fear that one's abilities might be demonstrated to be suboptimal. The latter may be particularly relevant if there are financial or service imperatives to continue with the status quo. Nevertheless, we owe it to our patients to overcome these barriers to ensure that endoscopy is of the highest quality.

ESGE and UEG have identified quality of endoscopy as a major priority. We recommend that all units develop mechanisms for audit and feedback of endoscopist and service performance, using the ESGE performance measures that will be published in future issues of *Endoscopy* over the next year. Regional and national organizations have a responsibility to support and, where required, provide resources for such quality improvement initiatives. We urge all endoscopists and endoscopy services to prioritize quality and to ensure that these performance measures are implemented and monitored at a local level, so that we can provide the highest possible care for our patients.(

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