II. 開発の現状：

この開発作業は、医療用具に関し現存する六つの各国分類集（米国 ECRI、米国 FDA、ﾉﾙｴｰNKKN、日本薬事法、欧州 EDMA、および ISO0999）を出典とする一万有余の医療用具の一般的名称を、世界各国から選任された約 50 人の専門家が各自のﾊﾟｿｺﾝと EC 委員会から事業を委任された英国の Medical Device Agency が設営したｵｯｸｽﾌｫｰﾄﾞ近郊にある GMDNﾃﾞｰﾀﾍﾞｰｽとを結び、前述の六つの各国分類集から抽出された関連部門英文用語を整理統一し、その中の代表的な用語の定義を行い、他の専門家および諮問委員会委員との検討を Web 上でおこなっている。

各専門家は、過去数度行われた GMDN 専用のｺﾝﾋﾟｭｰﾀ・ｿﾌﾄ操作の研修、各専門ｸﾞﾙｰﾌﾟ内での打合せや作業内容の討論のための会議への出席の上、各自国内での日常の編纂作業をおこなってきた。この編纂作業の指針とｶﾞｲﾄﾞのために、GMDN Project Manual が専門家に配布されている。読者のご参考のために、当報告者が意訳しここに添付する「GMDN ﾌﾟﾛｼﾞｪｸﾄ・ﾏﾆｭｱﾙ」をご参照乞う。

なお、 GMDN の完成予定は、当初 1999 年 11 月末であったが、作業が若干遅れており、GMDNﾌﾟﾛｼﾞｪｸﾄ評議会では、実際の完成時期を 2000 年 3 月頃と見込んでいる模様である。

V.　あとがき

この研究のために引用し訳文を付録資料に収載した文献の大部分は、ｸﾞﾛｰﾊﾞﾙ整合会議(GHTF)及び ISO/TC 210会議で得られた成果であり、内容を熟知している下記の研究協力者が、自ら会議に出席して討議に参加している点に本報告の特長がある。

分担研究者は、報告書の全体構成を担当した。

各章の執筆と関連す文献翻訳を、次に示す研究協力者に担当していただいた。

I.　吉田正人　　日医機協 ｸﾞﾛｰﾊﾞﾙ整合委員会 副委員長兼第一・第二分科会 主査
（旭ﾒﾃﾞｨｶﾙ㈱ 常務取締役 技術総括担当）

III. 二又紳一郎　ISO/TC 210 JWG1 合同作業分科会　幹事
（㈱東芝 医用ｼｽﾃﾑ社 那須工場 品質保証部品質保証ｸﾞﾙｰﾌﾟ 主務

IV. 番　和明　　日医機協 規制ﾃﾞｰﾀ交換ｼｽﾃﾑ検討分科会　副主査
（㈱日立製作所 計測器ｸﾞﾙｰﾌﾟ 医用ｼｽﾃﾑ本部 技術部 副参事）

終わりに、平素ご指導を頂く、ISO/TC 210 国内対策委員長 桜井靖久 名誉教授（東京女子医大）並びに日医機協 ｸﾞﾛｰﾊﾞﾙ整合部会長 高島史路氏（日本光電工業㈱相談役）に厚く謝意を表するとともに、報告書執筆並びに文献翻訳を担当した研究協力者の労を多としたい。

＜関連資料＞

1. 平成7年度報告　厚生科学特別研究
「医療用具の国際整合化のための基礎的調査研究」
2. 平成8年度報告　厚生科学研究
「医療用具の国際整合化のための個別的調査研究」
3. 平成9年度報告　厚生科学研究
「医療用具の国際的整合化のための個別的調査研究」
4. 平成10年度報告　厚生科学研究　(H10-医薬-031)
「医療用具関係の国際ﾊｰﾓﾅｲｾﾞｰｼｮﾝに関する研究」ISO/TC210及び GHTF関係

別紙２　　厚生科学研究費補助金（医薬安全総合研究事業）
分担研究報告書

医療用具関係の国際ハーモナイゼーションに関する研究

分担研究者：　佐々木次雄　国立感染症研究所　安全性研究部無菌性制御室長

研究要旨：ISO/TC198 で作成した滅菌法及び滅菌保証に関する国際規格を日本薬局方の「培地充填試験法」、「最終滅菌法及び滅菌指標体」、「最終滅菌医薬品の無菌性保証」作成に反映してきた。日医機協と国内医療用具メーカーにおける滅菌の現状調査を、また日薬連と国内製薬企業における高圧蒸気滅菌の現状について調査を行なった。

A．研究目的

ISO/TC198 で作成したヘルスケア製品（医療用具、医薬品、体外診断薬の総称）の滅菌法及び滅菌保証の国際規格を日本薬局方や厚生行政に反映させる。

B．研究方法

本年度は、１）ISO/TC198 会議の全体的動向を把握、２）国内医療用具メーカーに対して滅菌の現状について調査、３）国内製薬企業に対して高圧蒸気滅菌の現状について調査を行なった。

（倫理面への配慮）　特になし

C．研究結果

ISO 規格は５年毎に見直すことになっており、ISO/TC198/WG1（EOG）,WG2（照射滅菌）,WG3（高圧蒸気滅菌）の見直しが始まり、これらについて対応した。日医機協と国内医療用具メーカーにおける滅菌の現状調査を、また日薬連と製薬企業における高圧蒸気滅菌の現状について調査を行なった。これらの調査結果は、監視指導課から出ている滅菌バリデーション基準やガイドライン、滅菌医薬品に対するパラメトリックリリース要件に活用したい。

D．考察

分担研究者はこれまで、ISO 11737-1（バイオバーデン試験法）や ISO 13408-1 （ヘルスケア製品の無菌的製造法）の作成、ISO/WD 13408-2（ろ過滅菌法）のプロジェクトリーダー、 ISO11134（工業用高圧蒸気滅菌）の国内主査として、滅菌及び無菌性保証に関する国際規格作成に広く貢献してきた。これらの国際規格は、監視指導課から出ている滅菌バリデーション基準やガイドラインの他に、日本薬局方の「培地充填試験法」、「最終滅菌法及び滅菌指標体」、「最終滅菌医薬品の無菌性保証」作成に反映してきた。 ISO/TC198 で作成した国際規格を日本国内の業界に適切に伝え、厚生行政に反映させるためには、更なる努力が必要と考えている。

E．結論

医療用具に対する滅菌の現状調査及び医薬品に対する高圧蒸気滅菌の現状調査結果については、論文として国内外に広く伝えるとともに、問題点については監視指導課や審査管理課と相談し、解決を図りたい。ISO/TC198 の活動動向を適切に国内業界及び厚生行政に反映させるためには、ISO/TC198 国内対策委員会体勢の充実も必要である。

F．研究発表

１．　論文発表（ISO/TC198 関係）

１．佐々木次雄、三瀬勝利、中村晃忠編「日本薬局方に準拠した滅菌法及び微生物殺滅法」日本規格協会、1998 年。

２．佐々木次雄、川村邦夫、水田泰一編「国際規格に準拠した無菌医薬品の製造管理と品質保証」日本規格協会、2000 年。

３．佐々木次雄、医薬品研究（日本公定書協会）、日局解説書（広川書店）、他

学会発表

シンポジウム、セミナー等で数多く発表

厚生科学研究費補助金分担研究報告書

インプラント用具の国際調和

（医療用具関係の国際ハーモナイゼーション
に関する研究）

平成１１年度厚生科学研究費

医薬安全総合研究事業

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厚生科学研究費補助金（医薬安全総合研究事業）
分担研究報告書

インプラント用具の国際調和

（医療用具関係の国際ハーモナイゼーションに関する研究）

分担研究者　佐藤　道夫　　国立医薬品食品衛生研究所 療品部 室長

研究要旨：国際標準化機構(ISO)のTC150(Implant for Surgery)における議論を通じて、インプラント用具のトラッキングの基本的な要素である埋植・摘出時に記録すべき最少限の事項に関する国際基準案の作成に関与した。現在、DISとなり完成に近づいている。また、摘出物の分析法に関する基準も一部はISOになるなど、基本的な部分は整備されつつある。さらに、摘出物に関しては米国NIHで技術会議が開かれ、今後の動向について活発な議論が行われた。筆者もインプラント・データベースの各国の動きや日本の現状について紹介した。

A．研究目的

医療用具分野での国際調和は各国の利害対立などが複雑にからんでいる。本研究は、インプラント用具の主要問題についての科学的裏付けについて、国際的な状況を紹介することを目的とする。

我が国においては、インプラント用具の内、特定医療用具のトラッキングは製造・輸入業者の義務とされているが、まだ成熟したシステムにはなっていないと思われる。そこで、トラッキングの基本的な要素である埋植・摘出時に記録すべき最少限の事項に関する国際基準案の作成を目指すことが第一の目的である。

また、これらの記録と共に、何らかの原因で体内から取り出された摘出物の分析は、用具の性能、安全性を評価する上で貴重な情報となる。しかし、統一のとれていない手法での分析結果は、比較が困難で、有効なデータとは成りにくい。従って、標準的な摘出物の取り扱い法、分析手法を確立することが非常に大切となる。これらについてのISOとNIHでの、動向を紹介したい。

B．研究方法

インプラント用具や循環器系用具のすべてを包含した国際標準化機構(ISO)/技術委員会 TC 150(Implants for Surgery: 外科用インプラント)における、直轄作業班 WG9(Minimum Data Sets for Surgical Implants) の議論に参加し、Minimum Data Set (埋植・摘出時に記録すべき最少限の事項)の作成に関わった。

同作業班 WG5(Retrieval and Analysis of Surgical Implants: 摘出物の分析)においては、大方の議論は既に終了して各国の投票のレベルにあるため、１昨年

度から打ち合わせ程度で会議は終始し、今年度はWG5そのものも開かれなかった。従って、現段階でのドラフトを紹介するに留める。

2000年１月10日より12日まで、米国NIHにおいて、NIH主催の技術評価会議 （Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities)が開かれた。筆者も講演依頼を受けて参加したため、この会議の内容を紹介する。

C．研究結果

TC150/WG9

1994年からインプラントデータについての国際会議が３回行われ、３回目の会議(1996.6, 米国, Buffalo)には筆者も参加して日本の実状を紹介した[1]。それらの結果を踏まえて、ISOでも埋植・摘出時に記録すべき最少限の事項 (Minimum Data Set)を作成すべく、TC150にWG9が設置された。１回目は1997年11月にシンガポールで開催され、２回目が1998年10月に、豪、米、スウェーデン、日、韓の5カ国の委員(議長は豪州厚生省の Brandwood氏)の参加により行われた。1997年の委員会草稿(CD)への各国からの意見を基に討議を重ね、DISの草案を作成した。議長による付録部分への追記、修正等を経て正式なDISになった後、各国への投票に委ねられ、Pメンバーでは全部賛成(19/19)、全メンバーでは22/23の賛成多数となったため、若干の編集を経て、FDISに移行する予定である。内容については、議長の厚意でFDIS直前の草稿を入手できたため、参考資料として添付した[2]。

今年度10月に開催されたTC150総会においては、この議題について大きな変更意見が各国から出なかったため、WG9の開催は見送られた。

なお、TC150直轄のWG5とWG9は、統合されてWG10となり、WG5とWG9は廃止されて、両議長が、議長と副議長を勤めることとなった。また、これまでのWG1～WG9は、全て廃止となった。

幸いにも両会議に参加する機会を得ることができたため、その詳細を以下に述べる。

Minimum Data Setを設定する目的は、登録(レジストリ)、患者追跡(トラッキング)、及び摘出物の分析のために、データの記録や国際的なデータ交換を容易にするためである。データの記録は製造・流通業者、医療機関(埋植、摘出)で行う。データは用具のリコールや不具合時の患者のフォローアップに対するトラッキングに用いられる。また、摘出物の分析に必要なデータの参照にも役立つ。これらのデータはあくまでも患者のフォローアップに使うのが目的であって、医師や医療機関、製造業者の検索を意図してはいない。これらのデータは第３者機関による電子的な検索を行う場合も想定している。

用具の供給者が記録保持すべき項目としては、

a)用具の流通鎖の一つ前の供給者(製造者は製造者自身)のidentity
b)用具の供給先のidentity
c)用具名とカタログ番号(用具型式を特定できる情報)
d)シリアル番号、ロット番号、バッチ番号など個別用具を特定できる情報

の４項目が挙げられている。なお、流通

の途中で用具名等が変更された場合は、変更前の記録とのリンクが必須である。基本的に用具の流通鎖において迅速な用具の追跡が可能になるようになされるべきである。

医療機関が記録維持すべき項目としては、

a)埋植・摘出が行われた場所
b)埋植・摘出が行われた日付
c)担当医師のidentity
d)患者のidentity
e)用具の供給者のidentityと住所
f)用具名とカタログ番号(用具型式を特定できる情報)
g)シリアル番号、ロット番号、バッチ番号など個別用具を特定できる情報
h)手術適応(リストからの選択可)
i)埋植体内位置(可能であればsideも明記)
j)摘出時の体内位置

の10項目が挙げられている。また、両者とも最初の製造業者についても記録するべきであり、これらのデータは各用具にとって適切と考えられる期間は保持する必要がある。

付録として、これらの記録手段としてバーコードの利用を推奨している。

２回の会議を通じて話題に載った事項は以下の通りであった。

○用具の供給業者による再包装が大きな問題で追跡が困難になる。供給業者の倒産もあり得る。これらを考慮し、用具の流通鎖に関する概念を導入した。

○箱のみにラベルされている場合は単品がバラバラになったときに識別が困難であるため、単品にラベルを付けることが望ましい。また、パーツが別々に使用されることを考慮する必要がある。

○医療機関の定義を病院や手術を行うところから、患者レコードを保持するところとした。医療機関において、患者のカルテを個別の医師が管理している場合は、病院が用具の供給者になるケースもあり得る。

○保存期間を明記すべきで、例えば15年としたらどうかという意見もあったが、15年では不十分な用具もあり、また用具によって期間が異なることも考慮し、適切な期間という表現にした。

○埋植データの記録は義務とするが、摘出については、わかる範囲で記述する。

○医師名については、明記する案から削除する案まで出て、かなりの議論があった。結局、病院がカルテを持っておらず個別医師がカルテを管理している場合は、その医師が医療機関に相当することになり、医師のidentityは当然記載される事、また医師の責任追及に使用されてしまう懸念がある事、等からCDでの記載は見送られた。しかし、DISの各国投票の段階で記載を求める意見が再燃し、結局、医師のidentityとして記載されることになった模様である。

○患者のIDについては、種々の議論があった。豪州ではMedicare Cardがあり、米国ではSocial Security Noがある。前者は保険制度と密接にリンクしていてバーコードも内蔵しており、非常に有効だが、後者は使用目的に制限があり、今回の目的には使用できないようである。統一されていることが望ましいが、各国によって事情が異なるため詳述はしないことにした。

○用具の効能、用途、使用上の注意などについても列記したらどうかという案が出たが、それらは最少データより拡張データとして捉え、別のデータベースとリンクすることで参照可能であることから採用されなかった。

TC150/WG5

摘出物の分析については、基本的な取り扱い法と共に、金属、ポリマー、セラミックスの４パートに分かれて記述されている。なお、生物由来材料についても、1998年に生体人工弁を中心とした素案が提出されたが、TC150において生物由来材料を取り扱う専門的素地がないこと、ISOとして標準化を行うには、まだ時期尚早であることなどから廃案となった経緯がある。また、複合材料についても当分、取り上げないことになっている。

セラミックス材料(DIS 12891-4)では、Pメンバー投票では賛成(15/15)で、全メンバーでも賛成(16/16)であった。一方、金属材料(FDIS 12891-2)、ポリマー材料(FDIS 12891-3)は、昨年末に投票が締め切られ、賛成多数でISOに指定される見込みである。これらの内容については、残念ながら版権の関係で参考資料に添付してはいないが、参考文献としてリストアップしておく[3-6]。

内容については、ポリマー材料を例に挙げて説明する。分析手法は材料特有の方法があり、それぞれ異なるが、考え方は共通である。

A)インプラント界面の分析

1)インプラントー組織界面

インプラント周辺組織中の微粒子の研究の他に、可能であればインプラントの分解産物の化学分析、インプラントに対する細胞反応などを考慮する。

2)インプラントーインプラント界面

ポリマーは柔軟な場合があるので、ポリマー同士の摩耗を考慮すべきである。

B)インプラントの分析

1)一般的方法

複雑な分析を伴うため３つのステージに分ける。また、分析手法は摘出理由を考慮すべきである。不具合が疑われる時などにはかなり踏み込んだ研究が望まれる。

2)標準書式

各研究ステージで記録される事柄について基本的な書式を示す。

3)ステージ１研究：巨視的試験(非破壊的)

○マークや番号などで用具の同定を行い、写真撮影を行う。

○用具表面を観察して不具合症状、表面形状の変化を探る。

○低分解能の実体顕微鏡などで観察する。

○さらなる研究が必要と判断されるか不具合症状があればステージ２に進む。

4)ステージ２研究：微視的試験(概ね非破壊的)

○通常の光学顕微鏡か走査電子顕微鏡で観察し、可能であれば、偏光、位相差顕微鏡を使用する。

○用具に疵等が観察された場合は、できるだけ非破壊的な手法で表面を検査する。

5)ステージ３研究：材料試験(概ね破壊的)

○用具の評価に必要とされた場合に行う。

○物理化学的な手法で材料を特定する。

例えば、示差熱分析、分子量分析、IR

等の分光分析が有用となる。ポリマーによってはスライスでの顕微鏡分析が有効である。用具の分析採取位置を明記しておく必要がある。当然、分析法も詳述する必要がある。バルクと表面とでは性状が異なることも考慮すべきである。

○密度と堅さを材料標準に則って測定する。必要であれば、引っ張り、曲げ、圧縮強度を測定する。この際、用具のサイズ、形状を十分に考慮する。

○転移温度、融解熱等の熱的測定を行う。

○ポリマーからの溶出物測定を行う。

6)表面処理被覆インプラント関連規定

表面処理が施された用具の場合は、表面処理状態の変化を観察する。剥離層等の記録と周辺組織との関連を調べる。

7)生分解性インプラント関連規定

用具の構造的な保全性、特に表面の疵、層間剥離、等の変化について調べる。また、周辺組織との関連を調べる。

C)インプラントの性能

不具合症状がある時は、用具の適応、生理的条件、病歴、荷重等について考慮すべきである。

付録Aとして、摘出ポリマー材料インプラントの分析ガイドの標準書式が、また、付録Bとして、ポリマー材料の評価試験方法が記述されている。

NIH/技術評価会議

今回は、インプラント用具の摘出に関しての会議であったが、当会議以外にも、過去にNIHの予算で種々の分野で開かれており、今後の科学技術の方向に対する勧告を行っている。当課題に利害関係のないパネリストと各分野の講演者を招待して、公開（インターネットによるリアルタイム中継を含む）で会議を開き、演者の講演、パネルおよび聴衆からの質問等が終了後、パネルが草稿を作成し、これに関して最終日に議論を行って最終的にまとめるという会議であった。 News Release[7]と Draft Statement[8]は会議後に送られてきたが、同一の内容がNIHのWebページにも掲載されており、参考資料としては、空白部分が少ない後者を掲載した。会議の勧告は、Draft Statementの最後に記述してある通りで、要約すると次のようである。

1)NIHとFDAは、今後も同様の会議のスポンサーとなること。

2)臓器ドナーカードのように埋植時には患者にカードを発行すること。解剖摘出時にも役立つ。

3)患者、行政、医療機関、製造業者に対して、用具の摘出と分析の重要性を知らせる教育システムを作ること。例えば、Webサイトを作り、用具のデータベースとリンクさせる等の方法が考えられる。

4)製造業者は不具合情報を提供すること。

5)学会に各領域からなるフォーラムを作るよう押し進めること

6)NIHに摘出物の分析トレーニングコースを作ること。

以上であった。

筆者は主として日本の紹介を行った[9]。参考資料の講演要旨には英国の紹介も記載したが、急遽、英国の演者が講演を行ったため、講演では省略した。

また、会議翌日の新聞に掲載されたものを資料として添付した[10]。会議直後に記者会見を行ったため、各新聞に掲載さ

れた模様であるが、筆者が入手できたのは、この資料だけである。

D. 考察

ISOでのMinimum Data Setの標準化は、ほぼ完成に近づいており、今後は細部の修正に留まるものと思われる。今回の項目は最少限のものであって、特別なものではない。当然の事ながら、日本国内の医療機関、用具の供給業者でも、既にこれらのデータの全て、或いは一部を記録保持しているものと推測される。特定医療用具に関しては、同様の内容を保存することが義務でもある。しかし、電子化にはなかなか至っていないようである。今後は、患者のプライバシーには十分配慮しつつ、現場での容易な記録と、万一の場合の患者の迅速なフォローアップが可能になる様、患者及び用具のIDのコード化、バーコード等による入力法の機械化、そして記録保持法の電子化、を目指してゆく必要があろう。

摘出物の分析も、まだ基本的な手法の提言に留まっているものの研究方法の国際的な標準化が進み、米国でも本格的に取り組む姿勢が見られる。米国では、おそらく研究予算が従来以上に増額されるであろう。国際的な情報交換と共に、日本でも一部の用具で進められている全国的な摘出物収集・分析システムが、種々の用具でも本格化されることが望ましい。

この研究に当たって、協力を惜しまなかったTC150 WG9の議長である豪国 TGAのBrandwood氏に深謝したい。

E. 結論

トラッキングの基本的な要素でもある、埋植・摘出時に記録すべき最少限の事項に関する国際標準化機構における議論を通じて、国際基準案の作成に貢献できた。また、摘出物の分析法に関する基準も基本的な部分は整備されつつある。摘出物に関しては米国NIHで技術会議が開かれ、今後の動向について活発な議論が行われた。筆者もインプラント・データベースの各国の動きや日本の現状について紹介した。

F. 参考資料

1. Michio Sato and Akitada Nakamura, "Device Tracking and Retrieval in Japan", Proceedings of IDr3 - Implant Data: Record, Report, Review, 1996.
2. ISO/TC150/DIS 16054 "Minimum Data Sets for Surgical Implants", ISO/DIS 16054 の草稿. (資料添付)
3. ISO/TC150/ISO 12891-1 "Retrieval and Analysis of Surgical Implants - Part 1: Retrieval and handling"
4. ISO/TC150/FDIS 12891-2 "Retrieval and Analysis of Surgical Implants - Part 2: Analysis of retrieved metallic surgical implants"
5. ISO/TC150/FDIS 12891-3 "Retrieval and Analysis of Surgical Implants - Part 3: Analysis of retrieved polymeric surgical implants"
6. ISO/TC150/DIS 12891-4 "Retrieval and Analysis of Surgical Implants - Part 4: Analysis of retrieved ceramic surgical implants"
7. NIH News Release - "Expert Panel Identifies Major Challenges and

Opportunities for Improving Medical Implant Retrieval and Analysis (Wednesday, January 12, 2000). (資料添付)

8. DRAFT STATEMENT, 19. Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities, NIH, NIH Technology Assessment Conference Summary, January 10-12, 2000. (資料添付)

9. Michio Sato, "Current Accessible Databases Around the World", Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities, NIH, 2000. (資料添付)

10. "A Body of work in spare parts", USA Today, January 13, 2000. (資料添付)

ISO/TC 150

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Implants for surgery — Minimum data sets for surgical implants

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Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 16054 was prepared by Technical Committee ISO/TC 150 *Implants for surgery*. This is the first edition of this International Standard.

Annex A of this International Standard is for information only.

Introduction

The importance and utility of registry, tracking and retrieval analysis systems in understanding long term clinical performance of implant devices and in patient follow up in the event of unforseen device malfunction is understood. This International Standard addresses the minimum information concerning the patient, the device manufacturer and the clinical and surgical procedures which needs to be collected to ensure efficient and rapid international patient follow up should it be required. It also provides the core data set to allow linkage of different registries for the purposes of retrieval analysis.

Competent Authorities and medical device regulators should consider inclusion of these minimum data requirements as a progression into the distribution chain to the end user of the requirements of ISO 13485.

Users of this International Standard are advised hat it is possible to collect all of the data items specified in this International Standard and if desired to transfer these data to third party registers using automated methods. An informative annex to this International Standard provides references to technical standards which define mechanisms for automation of both data collection and transmission.

Implants for surgery — Minimum data sets for surgical implants

1 Scope

This International Standard defines minimum data sets to facilitate recording and international exchange of data for the purposes of registry and tracking systems and for retrieval analysis. Minimum data collection requirements are specified for the purpose of implant tracking to allow recall for product correction or patient follow up in the event of unforseen device malfunction. The minimum data set also fulfills the core data requirements to allow cross referencing between extended data sets for the purposes of retrieval analysis and research.

This International Standard is applicable to the manufacturers and distributors of permanently implantable medical devices and to those hospitals and other medical facilities which carry out implant procedures. It specifies requirements for data items to be recorded by the manufacturers and distributors of permanently implantable medical devices and by hospitals and other medical facilities at both the time of implant and at the time of any subsequent explant procedure.

It is intended that this International Standard provide for the capture of a defined minimum data set for all implant and explant events. This International Standard provides for the timely retrieval of minimum implant data related to specific subsets of patients who have received specific identified devices or devices within a specified range of lot, batch or serial numbers, for the purpose of patient follow up.

It is not the intent of this International Standard to provide a means of data recovery which is related to specific medical practitioners, medical facilities or manufacturers for purposes other than patient follow up.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 13485, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001*

ISO 8402, *Quality management and quality assurance — Vocabulary*

NOTE Users of this standard should ensure compliance with appropriate national standards or regulations concerning data protection and handling.

3 Terms and definitions

For the purposes of this International Standard, the definitions given in ISO 13485 and ISO 8402 apply, with the exception that the definition of "implantable medical device" given in ISO 13485 is modified for the purposes of this standard to include active implantable medical devices. In addition the following definitions apply.

3.1
implantable medical device
an implantable medical device is defined according to the requirements specified in ISO 13485, with the exception that for the purposes of this International Standard, the definition also includes active implantable medical devices as defined in ISO 13485.

For modular implantable medical devices which are supplied to the medical facility either separately or as kits, each separately supplied component or each separate item of a kit shall be considered to be a unique and separate implantable medical device subject to recording as unique and separate implant and explant events. Examples of separate modular components are:

— the pulse generator and electrode lead(s) of an implantable cardiac pacemaker or defibrillator and

— the cement and each of the separate components of a modular hip prosthesis.

NOTE ISO 13485 gives a separate definition for **active implantable medical devices** and specifically excludes these from the definition for **implantable medical devices**. The above definition differs from that given in ISO 13485 in that the separate definitions for **implantable medical devices** and **active implantable medical devices** are combined into one.

3.2
implant event
the act of surgical intervention by which an implantable medical device is

- totally introduced into the human body or
- used to replace an epithelial surface or the surface of the eye, or
- partially introduced into the human body

and which is intended to remain in place after the procedure for at least 30 days and which can only be removed by medical or surgical intervention.

3.3
explant event
the act of surgical intervention by which an implantable medical device is removed from a patient.

3.4
medical facility
the person or organisation which is responsible for maintaining the patient record.

NOTE 1 The medical facility is also, by definition, the final **customer** (ISO 8402) in the distribution chain.

NOTE 2 In some cases hospitals may be considered suppliers, for example where patient records are the sole responsibility or individual surgeons practising within the hospital.

4 Data sets

4.1 Supplier data

The data items (a) – (d) as follows shall be recorded and retained by each supplier in the distribution chain.

NOTE The data may be transmitted to a third party registry for archiving purposes.

a) The identity of the previous supplier in the distribution chain.;

b) Customer identity;

c) The device name or description and catalogue number as given in the product information of the previous supplier which uniquely identifies the type of device;

d) Serial number or lot or batch number sufficient to identify the device to a level of the unique lot or batch or device.

Where a supplier allocates new product catalogue numbers, device names or descriptions, or serial, lot or batch numbers, that supplier shall maintain records which link the new identifiers with those provided by the previous supplier in the distribution chain.

Independent records of each separate supplier in a distribution chain shall, where known, include the identity of the original producer of the implantable medical device and those known to be in the supply chain.

Supplier data records shall be maintained in such a way as to allow timely traceability of the implantable medical devices through the distribution chain.

4.2 Medical facility data

The data items (a) - (j) defined as follows shall be recorded and retained by the medical facility for each separate implant event.

For explant events, as many of the data items (a) - (i) as can reasonably be determined shall be recorded.

These data should be maintained in such a way as to allow timely retrieval of the following data items for a set of patients which have been implanted with a specific device type or a specific range of lot, batch or serial numbers.

NOTE The data may be transmitted to a third party registry for archiving purposes.

a) Place of implant event or explant event;

b) Date of implant event or explant event;

c) Identity of the responsible clinician;

d) Patient identity;

e) Supplier identity and address;

f) The device name or description and catalogue number as given in the supplier's product information which uniquely identifies the type of device;

g) Serial number or lot or batchnumber sufficient to identify the device to a level of the unique lot or batch or device;

h) Primary indication for implant or explant, which may be selected from a predefined list;

i) Anatomical location of implant, including side where applicable;

j) Disposition (location or storage) of the explanted device.

Medical facility records shall, where known, include the identity of the original producer of the implantable medical device and those suppliers known to be in the supply chain.

Medical facility data shall be maintaines in such a way as to allow expeditous traceability of the implantable medical devices. Data shall be maintained for a period appropriate to the device.

Annex A
(informative)

Automated device labelling and data capture

Users of this International Standard are advised that the collection of the data items specified in this International Standard and if required, the transmission of these data to third party registers may be achieved by automated methods. This annex provides reference to other publications which provide specifications for automated data collection methods and for formats for electronic data interchange.

1) EAN/UPC Application Identifiers and FACT Data identifiers (NP 15418)

2) Bar coding - Symbology Specification - EAN/UPC (NP 15420)

3) Bar coding - Symbology Specification - Code 128 (NP 15417)

4) The Health Industry Bar Code (HIBC) supplier labeling standard

5) HL7: Application Protocol for Electronic Data Exchange in Healthcare Environments.

6) HL7's Implementation Support Guide

7) Appropriate standards under development by ISO/IEC JTC1/SC 31.

NIH NEWS RELEASE

NATIONAL INSTITUTES OF HEALTH — Office of the Director, NIH

FOR IMMEDIATE RELEASE
Wednesday, January 12, 2000

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Expert Panel Identifies Major Challenges and Opportunities for Improving Medical Implant Retrieval and Analysis

Heart pacemakers, artificial joints, intraocular lenses, and other medical implants are widely used in the United States, where an estimated 8 to 10 percent of the population has a medical implant. However, medical implant recipients often have unrealistic expectations of the risks and benefits associated with those implants, a technology assessment panel convened by the National Institutes of Health (NIH) has concluded.

The independent, non-Federal panel consisted of experts from the fields of medicine, engineering, law, and academia. It heard presentations on opportunities for and challenges of developing a formal system for retrieving and analyzing these devices. The lack of such a system has impeded research in this area.

"Many people understand that medical implants improve quality of life, " said panel co-chair, Edward N. Brandt, Jr., M.D., Ph.D. of the University of Oklahoma Health Sciences Center. "Far fewer recognize the importance of retrieving and analyzing medical implants when they fail or no longer are useful."

Retrieval and analysis of medical implants provides critical information for improving implant design and function and is vitally important to improve care of patients who need implants, the panel concluded in a statement released at the end of a NIH Technology Assessment Conference titled Improving Medical Implant Performance Through Retrieval Research Information: Challenges and Opportunities. The conference was held January 10-12, 2000 in the Natcher Conference Center on the NIH campus in Bethesda, Md.

To address issues regarding patient expectations, the panel recommended that the informed consent process prior to receiving an implant include discussion of benefits, risks, potential complications, expected longevity of the device, need for follow up, and possible future examination of the implant. The panel also urged that attention be directed toward reducing legal and economic disincentives to medical implant retrieval and analysis.

The panel stressed the need for comprehensive education programs to inform the public and professionals about the importance of medical implant retrieval and analysis.

"The NIH has an exceptional opportunity to improve care of patients with implants by providing education to all parties involved in the process," said Julia R. Weertman, D.Sc., panel co-chair, of Northwestern University. She added that retrieval analysis should be conducted with the full collaboration and participation of the medical device industry.

In its conclusions, the panel noted that tissue engineering is emerging as a new and promising area of medical implant science and recommended that the U.S. government begin active preparation and planning to construct the new regulatory protocols required by this new class of implants. In addition, the panel called on NIH to develop an aggressive research and development program to ensure continuing advances in medical implant science.

The full NIH Technology Assessment Statement on Improving Medical Implant Performance Through Retrieval Research Information: Challenges and Opportunities, is available by calling 1-888-NIH-CONSENSUS (1-888-644-2667). The statement also will be posted to the NIH Consensus Development Program Web http://consensus.nih.gov/ by Thursday, January 13, 2000.

The NIH Consensus Development Program was established in 1977 as a form of "science court" to resolve in an unbiased manner controversial topics in medicine. To date, NIH has conducted 111 such conferences addressing a wide range of controversial medical issues important to health care providers, patients, and the general public. An average of six conferences are held each year.

The conference was sponsored by the NIH Office of Medical Applications of Research and the National Heart, Lung, and Blood Institute. Conference cosponsors included the NIH Biomaterials and Medical Implant Science Coordinating Committee, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Dental and Craniofacial Research, the National Institute of Neurological Disorders and Stroke, the National Library of Medicine, and the National Institute of Standards and Technology.

NOTE TO RADIO EDITORS: An audio report of the conference results will be available from 4:00 pm ET January 13, 2000 through January 21, 2000 from the NIH Radio News Service by calling 1-800-MED-DIAL (1-800-633-3425) or by visiting http://www.radiospace.com/nihhome.htm on the Web.

[DRAFT STATEMENT]

19. Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities

National Institutes of Health
NIH Technology Assessment Conference Summary
January 10-12, 2000

NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.

Introduction

Medical implant devices (MIDs) have been used widely for more than 40 years, and it is estimated that 8 percent to 10 percent of Americans (20-25 million people) currently have such a device. Although implant devices have produced great benefits, it must be recognized that all MIDs are subject to failure. They are in a continual state of development to improve their performance and extend their useful lifespan. Long-term data on the behavior of implanted devices and host response are essential inputs to the development process, yet there are no systematic programs for the retrieval and analysis of implants in this country. Independent data banks do exist. The contributions to implant design provided by retrieval and analysis will benefit patients through improvements in implant performance.

For the purpose of this conference, implants are defined as having a minimum lifespan of 3 months, as penetrating living tissue, as having a physiologic interaction, and as being retrievable.

A number of barriers exist to the establishment of an implant retrieval program. Major impediments are the costs associated with such a program and the fear of litigation affecting manufacturers, hospitals, physicians, and investigators.

This conference is therefore timely and important. The panel addressed the following key questions:

- What are the patient, health care provider, and societal expectations of the lifetime costs, risks, and benefits of medical implants?
- What are the legal, ethical, religious, cultural, public policy, and economic barriers to implant retrieval and reporting, and how can they be overcome?
- What information is necessary to evaluate and improve implant and material performance and device design?
- What can the role of information data systems be in educating the public, medical community, and policymakers about medical implants and retrieval?
- What future research and institutional support is necessary to ensure continuing advances in implantable devices?

Responses to these questions by an independent, non-Federal technology assessment panel are based on the study of pertinent written material from the medical/scientific literature and on 1½ days of presentations by experts and audience discussion.

The primary sponsors of this conference were the National Heart, Lung, and Blood Institute (NHLBI) and the NIH Office of Medical Applications of Research (OMAR). Additional sponsors were the NIH Biomaterials and Medical Implant Science Coordinating Committee (which represents all of the NIH Institutes and Centers), the National Institute of Arthritis and

Musculoskeletal and Skin Diseases, the National Institute of Dental and Craniofacial Research, the National Institute of Neurological Disorders and Stroke, the National Library of Medicine, and the National Institute of Standards and Technology.

▲

1. What are the patient, health care provider, and societal expectations of the lifetime costs, risks, and benefits of medical implants?

Costs

The type or presence of health insurance and coverage provided likely modifies patient expectations of costs of implants. For life-saving devices that are not experimental or newly introduced, a patient should expect insurance coverage. Patient expectations of implant costs should include medications needed, if any, as well as coverage for explantation or revision, if necessary. Patients should not have to encounter unanticipated costs of revision, complications, or prescription drugs.

Health care provider expectations of the costs of medical implants are difficult to assess because many health care providers are insulated from costs of devices. However, hospitals or health care organizations may restrict the use of devices to certain manufacturers in order to contain costs, and physicians may feel restrained to choose less expensive devices if reimbursements are constant for the operative procedure.

Societal expectations of the costs of medical implants should conform to those of similar or alternative treatments, if available, and should factor in benefits provided by the implant, including return to productive life.

Benefits

Although highly variable, patient expectations of the benefits of medical implants are often unduly high, for a variety of reasons. Information presented to patients may be poorly understood, misleading, or inadequate. Expectations of medical implants vary according to the type of implant. Although there are gray areas and exceptions in individual cases, implants can be broadly categorized as form enhancing, life enhancing, or life saving. Expectations of the benefits of life-saving implants may be unduly high; for example, patients' perceptions of the benefits of artificial hearts and ventricular assist devices appear to exceed alternative therapies such as cardiac allografts (transplants). In general, patient expectations of life-enhancing or life-saving devices include survival, restoration of active lifestyle (function, quality of life, pain relief), gainful employment, and access to replacing the implant if necessary. The last expectation would also apply to form-enhancing implants.

Health care provider expectations of the benefits of medical implants are, and should be, similar to those of the patient. However, the patient's evaluation of the performance of an implant is different from that of the physician. For example, a patient may be satisfied by a hip replacement because of resolution of pain and enhanced range of motion. However, the physician may note x-ray abnormalities suggestive of imminent failure. Therefore, monitoring of implants needs to take into consideration perceptions of both physician and patient. Health care providers may also, in some cases, have a more short-term expectation of the benefit of the implant. Whereas the patient will expect benefits to persist for his or her lifetime, the physician may be satisfied with immediate relief of the patient's disorder.

Risks

As with the expectations of costs and benefits, expectations of risks of implants are greatly affected by the type of implant. For life-enhancing and especially form-enhancing implants, patients and physicians expect no catastrophic risks. For life-saving devices, patients and physicians understand there are risks; expectations are significantly affected by pre-operative education and the nature of the informed consent. It is also likely that cultural, socioeconomic, and ethnic considerations affect expectations of medical implants, but there are few data to support this contention. Health care provider expectations of risks of medical implants may, as in the case of benefits, be somewhat more short term than those of the patient. However, with optimal patient-provider communication and informed consent, the expectations of the physician and patient should become closer.

▲

2. What are the legal, ethical, religious, cultural, public policy, and economic barriers to implant retrieval and reporting, and how can they be overcome?

Implant retrieval and analysis is currently conducted on an ad hoc basis by implant manufacturers and academic health care institutions. Such analyses may provide the best opportunity to understand the long-term consequences of implantation and provide input to the evolutionary development of future implant technology.

A number of obstacles inhibit such studies, including limited availability, concerns about tort liability, and costs, but inasmuch as studies are already being done, it is axiomatic that these obstacles are not insurmountable. Why implant retrieval and analysis does not occur on a more widespread and routine basis is a matter which requires attention.

Legal

Commentators have identified a number of legal obstacles or disincentives to implant retrieval and analysis. First, uncertainties exist about who owns an implanted device. As with other questions about the bundle of rights protected by property law, a number of parties may assert an interest in a

device, and the resolution of disputes about ownership will depend to some extent on the terms of contractual agreements among these parties. Ultimately, however, the issue has less to do with ownership, as such, than with custody and control of potentially relevant evidence.

If litigation is pending or reasonably can be anticipated, persons must preserve potentially relevant evidence so that parties not in possession may view it and, subject to court-ordered restrictions, engage in destructive testing. Even if litigation is not pending, entities in possession of an explant may avoid engaging in retrieval analysis because of fear of the prospect of subsequent litigation and charges of intentional destruction of evidence. If entities with possession of explanted devices can safely engage in retrieval analysis, the prospect of litigation still may discourage attempts to retrieve devices in the first place or to analyze implants when available. Because of the inapplicability of the "self-critical analysis" privilege, potential defendants will hesitate to generate internal documentation of implant performance that plaintiffs may then request during discovery and introduce as evidence. Finally, independent researchers may hesitate to undertake implant retrieval and analysis either because litigants may subpoena their work or manufacturers may threaten product disparagement lawsuits if unflattering results are published.

Several commentators have asserted that tort litigation stifles technological innovation and continues to cause unavailability of certain raw materials, and it may well create disincentives to more widespread implant retrieval and analysis. This subject deserves further research and possibly legislative attention. Notwithstanding the potential enormity of such an undertaking, health care practitioners and researchers have an important opportunity to influence some of these legal disincentives by defining the standard of care in a manner that may facilitate medical device research and improvement. Health care professionals already have an ethical obligation to report adverse events and device malfunctions, and explanting surgeons and facilities at least should not inhibit efforts at retrieval analysis.

Finally, regulatory requirements may impede or discourage implant retrieval and analysis. The FDA could mandate that manufacturers conduct such research as a condition of premarket approval or as an element of a postmarket surveillance order, but it has exercised such authority only rarely. The FDA's quality system and medical device reporting requirements may influence manufacturers' decisions about whether to conduct such research voluntarily. If reported to the FDA, manufacturers may fear that proprietary retrieval information may be disclosed to the public if it does not qualify as trade secret or confidential commercial data. Conversely, independent researchers may find it difficult to link information about retrieved devices to the health records of patients because of expanding Federal and State privacy protections.

Religious

Among Roman Catholics, mainstream Protestants, and Orthodox Christians, there are no magisterial or in principle objections to retrieval of medical devices from living or dead human bodies for purposes of analysis and assessment. However, some Christian sects strenuously oppose any mutilation of the body, either before or after death. If pre- or post-mortem retrieval procedures are done in a timely manner (i.e., anticipating a prompt burial) and if the wound is sutured and the corpse treated with respect as though it were a living patient, liberal Jews-mostly Reform, Reconstructionist, and Conservative-have no objection on the principle of "pikkuah nefesh," the obligation to save life or lives. Such an act is a "mitzvah." Some Orthodox Jews and traditionalists, as a non-negotiable halachic norm, object to any mutilation of a corpse, including autopsy and embalming. Other religious groups have similar diversity of opinion.

Economic

There are clear and impressive economic barriers to retrieval of devices for analysis and assessment. Not least among these are costs associated with the project itself, and despite cost variables for different devices, financing is problematic.

Academic health care institutions' submissions of study proposals to funding agencies are not typically funded. Joint industry-academic efforts have been undertaken, but these are the exception rather than the rule. The ability of manufacturers to conduct their own studies relates directly to their size and in-house capability; the reality is that most of the medical device industry consists of small entrepreneurial companies without such a capability. There currently exists no industrywide "superfund" to support implant retrieval and analysis, but even if it were feasible to establish such a fund, these monies would not likely be sufficient to secure retrieval and analysis of every implanted device.

Likewise, funding for implant registries is difficult to obtain and sustain. Institutions and professional societies have supported limited patient registries/databases, and manufacturers have established patient registries both voluntarily and when asked or ordered to do so by regulatory agencies. Moreover, third-party registries have been attempted. Provisioning a universal data bank-with components for tracking and adequate representation of device and patient experience over time-appears to be prohibitively expensive at this time.

Analysis and assessment of medical implants currently poses significant liability risks for physicians and hospitals as well as manufacturers, and fear of costly litigation is a major barrier to retrieval. Exemption of some life-saving devices, as innovative or experimental therapies, from risk of liability would diminish that anxiety. Further, a publicly funded shared cost-charged, for example, in part to basic research and in part to applied technology-could facilitate a retrieval and analysis project. We need to understand why, in other sectors, technology reduces cost and increases market availability.

Economic factors can result in a lack of accessibility to some high-tech tertiary interventions by substantial segments of American citizens, particularly the poor and ethnic minorities. As a result, the findings from an implant retrieval and analysis program may not be applicable to underrepresented groups.

There is a strong sense that academic health care institutions would

conduct more and varied studies, either alone or in concert with Federal laboratories and/or manufacturers, were funding available. A continuation of an ad hoc approach, however, is not a viable means to meet the need for a coordinated implant retrieval and analysis system. Not only is funding needed, but that funding should be managed as part of an NIH/FDA joint program to develop uniform functional, quality-of-life, and analytical measures that would ensure intercomparability and sharing of data. Such an effort should also be in harmony with efforts globally.

An unexplored opportunity for funding is the third-party payer. As health maintenance organizations and other payers strive to contain costs while ensuring quality of health care, it becomes critical to conduct outcomes research. Implant retrieval and analysis, when coupled with information on the health status of patients at the time of explant, offers an opportunity to gather data in support of the cost-effectiveness of various implant technologies. The availability of chips that can monitor device performance, in ways similar to an airplane's "black box," suggests the possibility of a feasible cost.

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3. What information is necessary to evaluate and improve implant and material performance and device design?

Science progresses by facing its failures and learning from its successes. The goal of device research and development is to improve patient care through improvement of implants. A fundamental objective is to understand successful implants and assess failures through retrieval analysis. In addition, monitoring device performance in vivo may permit early corrective therapy. Explants will require specific analysis by qualified laboratories using appropriate protocols.

The information required to evaluate and improve implants is a combination of clinical data and device retrieval analysis.

At the Time of Implantation

The information should include (1) patient demographics, (2) primary diagnosis, (3) comorbidities, (4) patient-derived functional status if appropriate, and (5) date, location, surgeon, and specific implant data.

Following Implantation

The clinical status of the patient should be monitored by functional data, imaging, and internal monitoring via telemetry as appropriate.

At the Time of Explantation

Information needed at this time includes (1) patient demographics, (2) date, location, surgeon, and specific implant data, (3) clinical functional and imaging data acquired before explantation, (4) implant interrogation via internal monitoring/telemetry systems, (5) circumstances of explantation device failure or post-mortem retrieval of a well-functioning implant, and (6) device-specific information.

Explant Analysis

The explant analysis should begin with local pathological review followed by expert analysis by a qualified laboratory (manufacturer or independent). The appropriate studies of the implant should be done according to protocols, based on existing American Society for Testing and Materials (ASTM) and International Organization for Standardization (ISO) standards, where applicable, including biocompatability as judged by local and systemic (when available) tissue reaction.

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4. What can the role of information data systems be in educating the public, medical community, and policymakers about medical implants and retrieval?

Many people understand that MIDs provide improvements in quality of life for their recipients. Less widely recognized is the importance of the retrieval and analysis of a medical implant when it has failed or when it is no longer useful. Information gained from such retrieval and analysis provides insight into the strengths and weaknesses of the design of the device and enables improvement in future product design. Moreover, for those devices that have serious design flaws, retrieval and examination can yield insight into how to monitor patients who currently have the implanted device.

Education about retrieval and analysis for the various constituencies should take different forms because the needs of the constituencies differ. Patients and families must understand the purpose of retrieval to motivate their willingness to allow retrieval and analysis of the device. Policymakers must learn about retrieval to help them formulate wise policy. The medical community, that is, practitioners, administrators, and medical societies, should be able to use education about retrieval to help them treat current and future patients more effectively. Finally, device manufacturers will find the information gained from the study of explanted devices useful in the improvement of the next generation of devices.

Information about retrieval is most useful if it is placed in an appropriate context. Patients need to understand their disease and the options they have in choosing whether to have an implantable device. To make informed choices, patients must receive interpretable information that will allow them to develop reasonable expectations about the immediate, short-term, and long-term risks, the functional benefits arising from the device, and the lifespan of the device. The informed consent should be complete and clear. A primer describing the function of the device and possible failure modes will help patients understand the experience they are about to undergo. Finally, part of the educational process should be an explanation of retrieval of the product if it fails or if the patient dies before it fails. A fully informed patient