Status of Diagnostic Reference Levels in the US

Priscilla F. Butler, M.S., FAAPM, FACR, FSBI
American College of Radiology (retired)
Reston, VA

1

Co-author Acknowledgements

- K. Kanal from the University of Washington for leading the effort
- M. Chatfield, Dustin Gress and the team at the ACR Dose Index Registry for collecting and analyzing the DIR data
- D. Frush from Duke University for providing valuable clinical insight
- E. Samei, J. Wells and the team of the Duke University Clinical Imaging Physics Group for allowing the ACR to use their code to automatically determine patient size from localizer images in the ACR's Dose Index Registry

2

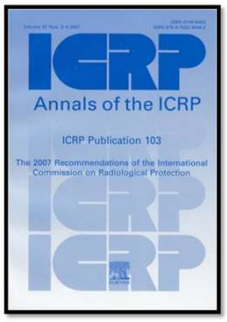
Here's My Checklist for Today's Topics

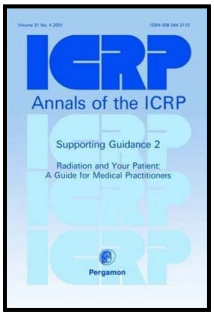
- ❑ Diagnostic Reference Levels (DRLs)
- ❑ ACR Dose Index Registry
- ❑ US Adult CT DRLs
- ❑ New US Pediatric CT DRLs
- ❑ Comparison of US DRLs with other Countries
- ❑ Wrap Up

3

Diagnostic Reference Levels (DRLs)

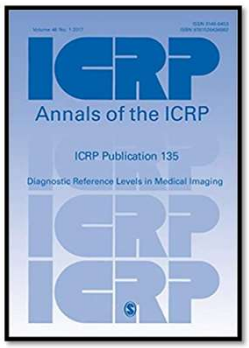
DRLs are investigational levels used to identify unusually high radiation doses for common diagnostic medical imaging examinations.





4

ICRP 135 (2017) – "How To"



- Methodology
  - ✓Easily measured – eg, $CTDI_{vol}$, DLP or SSDE (not effective dose)
  - ✓75th %tile of distribution of median values from all facilities
- DRLs are investigation levels
  - ✓Not regulations
  - ✓Not legal standards of care
  - ✓Do not apply to individual patients
- DRLs identify exams where levels of patient dose are unusually high
  - ✓If DRLs consistently exceeded, conduct review of procedures and equipment for optimization
  - ✓If not optimized, take action to reduce dose
- Overriding clinical objective - achieving acceptable image quality or adequate diagnostic information, consistent with the imaging task

5

ACR Dose Index Registry

NRDR
DIR®
DOSE INDEX REGISTRY
AMERICAN COLLEGE OF RADIOLOGY

6

ACR Dose Index Registry (DIR)

- Registry is a tool for quality improvement (launched in 2011) so facilities can review dose indices and optimize protocols
  - ✓Collects and compares dose index information across facilities
  - ✓Fully automated; uses standard methods of data collection and processing (DICOM SR, IHE REM Profile, RadLex)
- It does not collect individual patient doses; only dose indices:
  - ✓$CTDI_{vol}$
  - ✓Dose Length Product (DLP)
  - ✓Size Specific Dose Estimate (SSDE)
- It does not collect patient identifiable information
  - ✓It is not a mechanism to track individual patient dose
- It is not a census of all CT exams
  - ✓Participation in the registry is voluntary and fee-based

7

Registry Advantages for DRL Development

- Thousands of participating facilities
  - ✓From all practice types
- Millions of submitted examinations
- The huge exam volume in the DIR allows for size-based DRLs and ADs
  - ✓Remember, to get a diagnostic image

This guy needs a higher dose

Than this guy

8

US Adult CT DRLs

https://pubs.rsna.org/doi/epdf/10.1148/radiol.2017161911

ORIGINAL RESEARCH ■ MEDICAL PHYSICS

July 2017

U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations[1]

Radiology

Kalpana M. Kanal, PhD
Priscilla F. Butler, MS
Debapriya Sengupta, MBBS, MPH
Mythreyi Bhargavan-Chatfield, PhD
Laura P. Coombs, PhD
Richard L. Morin, PhD

Purpose: To develop diagnostic reference levels (DRLs) and achievable doses (ADs) for the 10 most common adult computed tomographic (CT) examinations in the United States as a function of patient size by using the CT Dose Index Registry.

Materials and Methods: Data from the 10 most commonly performed adult CT head, neck, and body examinations from 583 facilities were analyzed. For head examinations, the lateral thick-

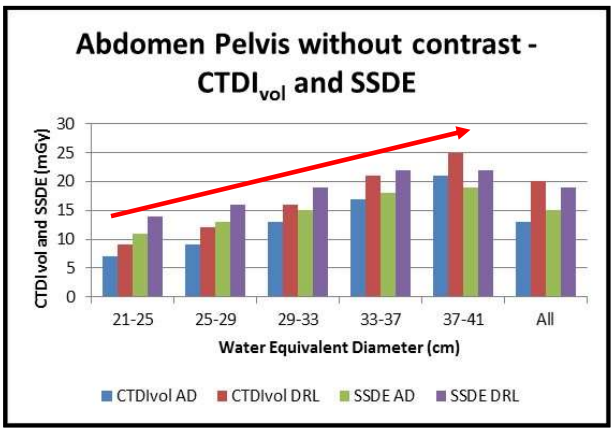
9

US Adult CT DRL and AD Summary
(Median Size Patients)

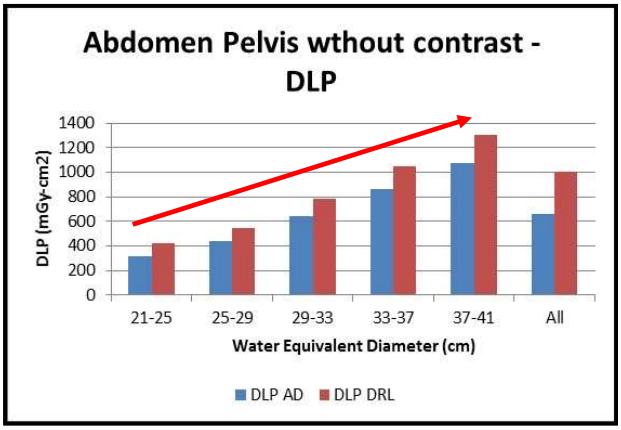
Examination	Median Patient Size (cm)	$CTDI_{vol}$ (mGy) DRL	$CTDI_{vol}$ (mGy) AD	DLP (mGy · cm) DRL	DLP (mGy · cm) AD
Head and brain without contrast	14-16	56	49	962	811
Neck with contrast	18-22	19	15	563	429
Cervical spine without contrast	18-22	28	20	562	421
Chest without contrast	29-33	12	9	443	334
Chest with contrast	29-33	13	10	469	353
Chest pulmonary arteries with contrast	29-33	14	11	445	357
Abdomen and pelvis without contrast	29-33	16	13	781	639
Abdomen and pelvis with contrast	29-33	15	12	755	608
Abdomen, pelvis and kidney without contrast	29-33	15	12	705	576
Chest, abdomen and pelvis with contrast material	29-33	15	12	947	779

Note: AD = achievable dose; $CTDI_{vol}$ = volume CT dose index; DLP = dose-length product; DRL = diagnostic reference level.

10



Larger Patients Need More Dose



11

11

New US Pediatric CT DRLs

https://pubs.rsna.org/doi/epdf/10.1148/radiol.2021211241

Radiology

ORIGINAL RESEARCH • PEDIATRIC IMAGING

U.S. Diagnostic Reference Levels and Achievable Doses for 10 Pediatric CT Examinations

Kalpana M. Kanal, PhD • Priscilla F. Butler, MS • Mythreyi B. Chatfield, PhD • Jered Wells, PhD • Ehsan Samei, PhD • Michael Simanowith, MD • Dan Golden, BA • Dustin A. Gress, MS • Judy Burleson, MHSA • William F. Sensakovic, PhD • Keith J. Strauss, MSc • Donald Frush, MD

Published online, October 27, 2021

12

Pediatric CT Exams in Study

- DRLs and ADs based on data from:
  - ✓Over 1.5M pediatric CT examinations
  - ✓Over 1600 facilities
  - ✓Acquired between 2016 to 2020

Body Part	Examination	# Exams*	%
Head	Head without IV Contrast	811,150	53
	Sinuses without IV Contrast	27,944	1.8
	Maxillofacial without IV Contrast	37,561	2.4
	Total	**876,655**	**57**
Neck	Neck Soft Tissue with IV Contrast	38,128	2.5
	C-Spine without IV Contrast	91,219	5.9
	Total	**129,347**	**8.4**
Chest	Chest without IV Contrast	24,682	1.6
	Chest with IV Contrast	47,546	3.1
	Total	**72,228**	**4.7**
Abdomen-Pelvis	Abdomen/Pelvis without IV Contrast	62,205	4
	Abdomen/Pelvis with IV Contrast	376,323	24
	Total	**438,528**	**28**
Chest-Abdomen-Pelvis	Chest/Abdomen/Pelvis with IV Contrast	26,777	1.7
	Total	**26,777**	**1.7**
Total:		**1,543,535**	**100**

13

Characteristics of Facilities, Examinations and Patients

Category	Characteristic	Facilities		Examinations	
		No.	%	No.	%
Facility category	Academic	154	9.5	198,239	13
	Community hospital	1,068	66	874,501	57
	Multi-specialty clinic	53	3.3	17,960	1.2
	Freestanding center	264	16	36,299	2.4
	Children's hospital	57	3.5	407,288	26
	Other	29	1.8	248	0.6
Examination volume (average number of examinations per month)	1-10	810	50	124,474	8.1
	11-<20	305	19	170,839	11
	21-<30	187	12	199,162	13
	31-<40	107	6.6	159,364	10
	41-<50	59	3.6	107,689	7
	51-<60	43	2.6	109,162	7.1
	61-<70	22	1.4	59,135	3.8
	71-<80	19	1.2	60,174	3.9
	81-<90	8	0.5	16,803	1.1
	91-<100	9	0.6	33,936	2.2
	>100	56	3.4	502,797	33
Age group (y)	0- <1 yr			173,087	11
	1- <5 yrs			158,069	10
	5- <10 yrs			191,269	12
	10- <15 yrs			305,069	20
	15 -18 yrs			716,041	46
Total:		**1,625**	**100**	**1,543,535**	**100**

14

US Pediatric DRL Groupings – Age-based

- Primarily based on international guidance (PiDRL and ICRP 135) and our radiologist's input
  - ✓Head:
    - 0 - <1 y
    - 1 - <2 y
    - 2 - <6 y
    - 6 - 18 y
  - ✓All other body parts:
    - 0 - <1 y
    - 1 - <5 y
    - 5 - <10 y
    - 10 - <15 y
    - 15 - 18 y
  - ✓DIR does not break out ages <1 y

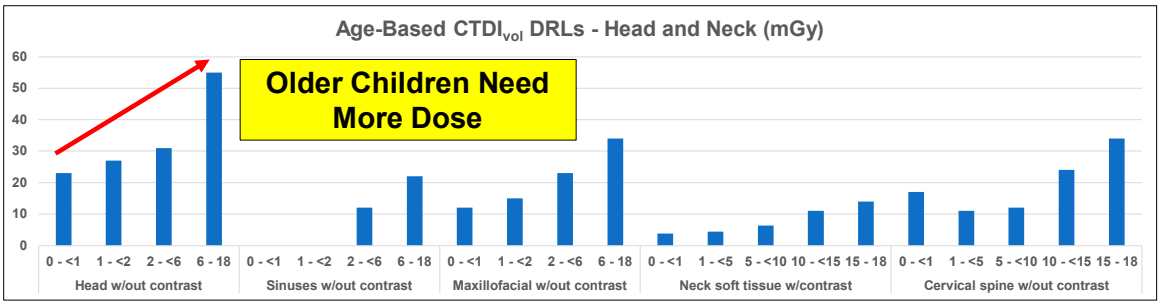
15

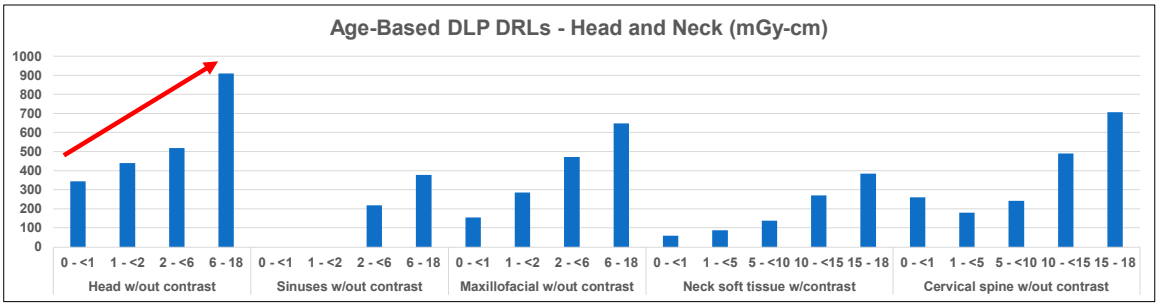
Example: Age-Based ADs and DRLs – Head & Neck

Examination	Age (y)	# Exams	$CTDI_{vol}$ (mGy)		DLP (mGy-cm)	
			AD	DRL	AD	DRL
Head without contrast material	0 - <1	66,307	19	23	267	344
	1 - <2	42,462	22	27	350	440
	2 - <6	108,808	25	31	409	518
	6 - 18	593,573	46	55	748	910
Sinuses without contrast material	0 - <1	-	-	-	-	-
	1 - <2	-	-	-	-	-
	2 - <6	2,234	6.7	12	94	219
	6 - 18	25,606	14	22	209	377
Maxillofacial without contrast material	0 - <1	917	6.3	12	103	155
	1 - <2	413	7.0	15	127	286
	2 - <6	2,488	11	23	196	472
	6 - 18	33,743	24	34	480	647
Neck soft tissue with contrast material	0 - <1	743	2.5	3.8	41	58
	1 - <5	7,502	3.4	4.4	65	88
	5 - <10	6,971	4.6	6.3	98	137
	10 - <15	6,491	7.8	11	198	270
	15 - 18	16,421	10	14	300	385
Cervical spine without contrast material	0 - <1	617	5.1	17	81	260
	1 - <5	4,010	4.7	11	67	179
	5 - <10	5,691	6.7	12	121	241
	10 - <15	18,798	13	24	284	490
	15 - 18	62,103	19	34	425	707

- Bin had fewer than 5 facilities reporting 20 or more exams

16





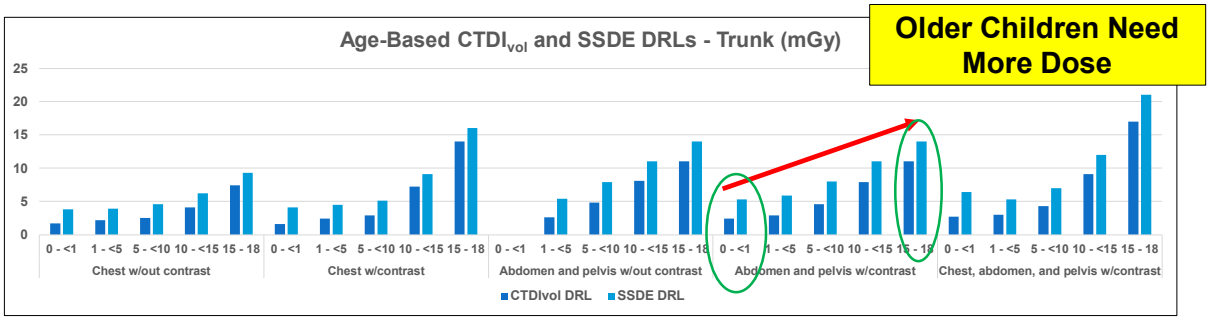
17

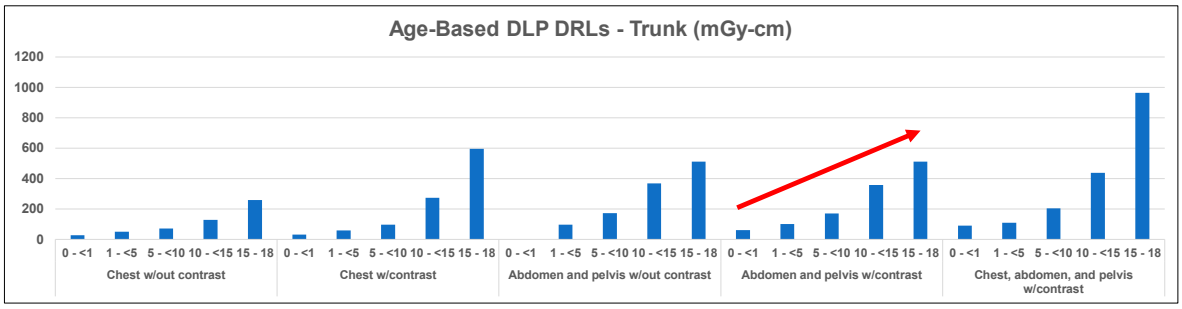
Age-Based ADs and DRLs – Trunk

Examination	Age (y)	# Exams	CTDIvol (mGy) AD	CTDIvol (mGy) DRL	SSDE (mGy) AD	SSDE (mGy) DRL	DLP (mGy-cm) AD	DLP (mGy-cm) DRL
Chest without contrast material	0 - <1	884	1.2	1.7	2.9	3.8	22	27
	1 - <5	3,110	1.7	2.2	3.3	3.9	35	49
	5 - <10	3,862	2.1	2.5	3.7	4.6	57	70
	10 - <15	6,639	3.4	4.1	5.1	6.2	107	128
	15 - 18	9,980	5.9	7.4	7.7	9.3	202	257
Chest with contrast material	0 - <1	2,653	1.4	1.6	3.0	4.1	23	31
	1 - <5	7,650	1.8	2.4	3.6	4.5	43	58
	5 - <10	7,264	2.3	2.9	3.8	5.1	64	95
	10 - <15	9,992	4.6	7.2	6.3	9.1	146	272
	15 - 18	19,453	8.8	14	11	16	364	596
Abdomen and pelvis without contrast material	0 - <1	-	-	-	-	-	-	-
	1 - <5	1,278	2.2	2.6	4.5	5.4	69	95
	5 - <10	5,058	3.4	4.8	5.9	7.9	124	171
	10 - <15	11,048	6.2	8.1	8.9	11	277	367
	15 - 18	43,747	8.4	11	11	14	408	510
Abdomen and pelvis with contrast material	0 - <1	1,886	1.8	2.4	4.2	5.3	49	60
	1 - <5	14,470	2.4	2.9	4.6	5.9	79	100
	5 - <10	49,323	3.3	4.6	5.8	8.0	126	170
	10 - <15	99,433	6.2	7.9	8.9	11	276	358
	15 - 18	208,728	8.3	11	11	14	402	511
Chest, abdomen, and pelvis with contrast material	0 - <1	505	2.0	2.7	4.4	6.4	62	89
	1 - <5	3,804	2.2	3.0	4.4	5.3	87	109
	5 - <10	3,770	2.9	4.3	4.7	7.0	142	204
	10 - <15	4,305	5.9	9.1	8.0	12	321	437
	15 - 18	14,071	12	17	14	21	691	964

- Bin had fewer than 5 facilities reporting 20 or more exams

18





19

US Pediatric DRL Groupings – Size-based (effective diameter)

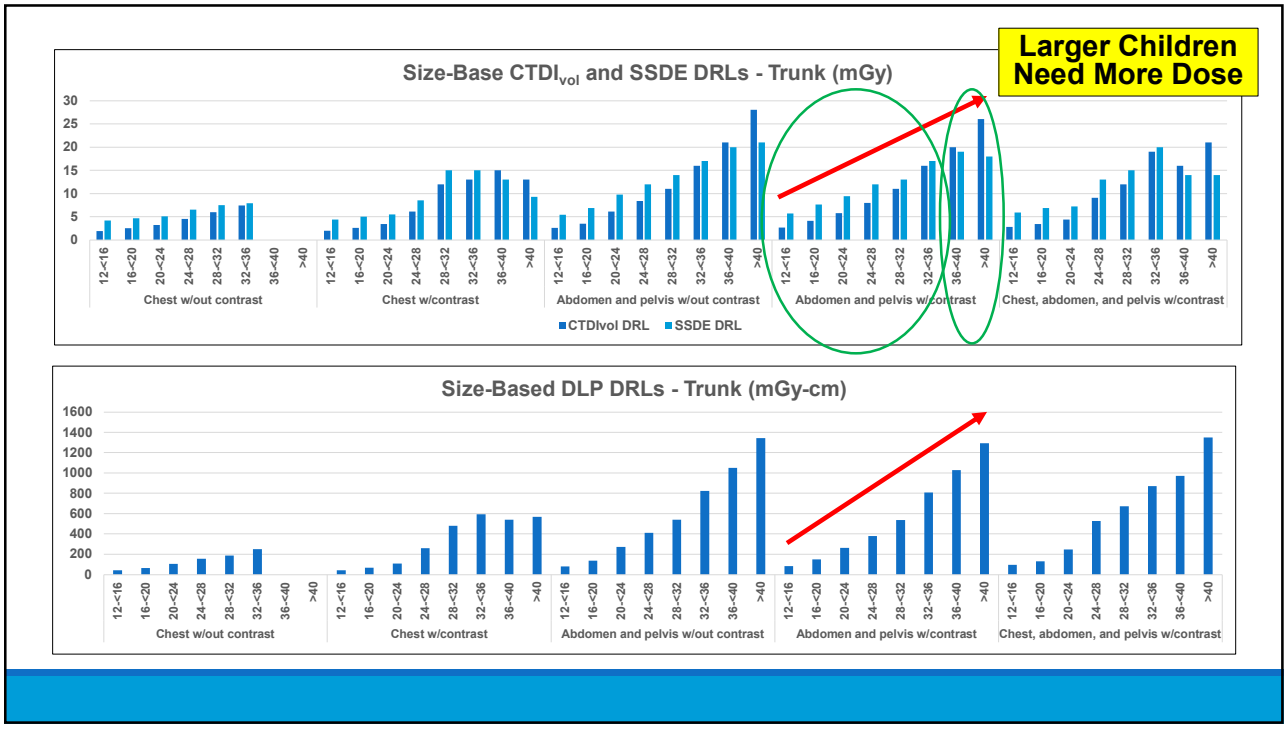
- Primarily based on US studies and adult DRL study extrapolation (international DRLs are weight-based)
  - ✓Uncertainty in head and neck size estimation due to inconsistent presence of shoulders in FOV precluded patient size analyses and SSDE reporting
  - ✓Trunk exams only
    - 0 - <12 cm
    - 12 - <16 cm
    - 16 - <20 cm
    - 20 - <24 cm
    - 24 - <28 cm
    - 28 - <32 cm
    - 32 - <36 cm
    - 36 - <40 cm
    - >40 cm

20

Size-Based ADs and DRLs – Trunk

Examination	Eff Dia (cm)	# Exams	$CTDI_{vol}$ (mGy) AD	$CTDI_{vol}$ (mGy) DRL	SSDE (mGy) AD	SSDE (mGy) DRL	DLP (mGy-cm) AD	DLP (mGy-cm) DRL
Abdomen and pelvis without contrast material	12-<16	501	2.1	2.6	4.6	5.4	58	79
	16-<20	1,845	2.7	3.5	5.1	6.9	96	137
	20-<24	4,425	4.8	6.1	7.7	9.8	199	272
	24-<28	8,870	6.4	8.4	9.1	12	287	409
	28-<32	4,289	8.9	11	11	14	423	538
	32-<36	1,242	13	16	14	17	677	824
	36-<40	319	17	21	16	20	910	1,050
	>40	658	24	28	15	21	1,155	1,342
Abdomen and pelvis with contrast material	12-<16	5,505	2.0	2.7	4.2	5.7	63	83
	16-<20	19,441	2.9	4.1	5.4	7.6	109	148
	20-<24	42,413	4.8	5.8	7.8	9.4	209	261
	24-<28	64,487	6.5	8.0	9.3	12	304	380
	28-<32	35,021	8.8	11	11	13	433	535
	32-<36	14,834	12	16	13	17	641	808
	36-<40	5,372	16	20	15	19	817	1026
	>40	5,391	21	26	15	18	1091	1292
Chest, abdomen, and pelvis with contrast material	12-<16	1,495	2.0	2.8	4.4	5.9	75	94
	16-<20	2,652	2.4	3.4	4.6	6.9	104	130
	20-<24	1,876	3.8	4.4	6.1	7.2	179	246
	24-<28	2,702	6.9	9.1	9.8	13	396	526
	28-<32	1,892	8.9	12	11	15	538	673
	32-<36	809	11	19	12	20	711	871
	36-<40	275	14	16	13	14	909	970
	>40	489	13	21	9.3	14	905	1,349

21



22

Comparison of US DRLs with Other Countries

Caution: Methodology and patient size groupings are not the same everywhere so be careful when comparing.

23

International Adult CT DRL Comparisons

Body Part	Procedure	Parameter	Diagnostic Reference Levels - $CTDI_{vol}$ (mGy) and DLP (mGy-cm)								
			ACR DIR (2016)[a]	Japan (2015)[d]	EU (2014)[e]	UK (2014)[f]	Ireland (2012)[g]	Australia (2011)[h]	Canada (2016)[i]	Netherlands (2012)[j]	Greece (2014)[k]
Head	Head Brain without contrast	$CTDI_{vol}$	56	85	60	60	58	60	79		67
		DLP	962	1350	1000	970	940	1000	1302		1055
Abdomen Pelvis	Abdomen Pelvis with contrast	$CTDI_{vol}$	15	20	25	15	12	15	18	15	16
		DLP	755	1000	800	745	600	700	874	700	760

[a] *ACR Dose Index Registry - DRLs are based on size bin containing median size patients*
[d] *Japan [19] - based on standard-sized patients (50 - 60 kg)*
[e] *European Union [20] - derived from "most common value" from surveyed countries*
[f] *United Kingdom [13] - no condition specified for patient size*
[g] *Ireland [21] - based on average-sized patients (60 - 80 kg)*
[h] *Australia [22] - no condition specified for patient size*
[i] *Canada [23] - based on average-sized patients (50 - 90 kg)*
[j] *Netherlands [24] - based on standard-sized patients*
[k] *Greece [25] - based on "typical" acquisition*

24

International Ped CT DRL Comparisons - Head

Exam	Parameter	Age Groupings (y) and National Pediatric Diagnostic Reference Levels															
		ACR DIR		Australia		Belgium		Canada		Germany		Japan		Korea		EU	
		Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL
Head without contrast	$CTDI_{vol}$ (mGy)	0-<1	23	0-4	30	<1	22	0-3	37	3 m-<1	30	<1	30	0	18	<3 m	24
		1-<2	27			1-<5	30			1-<5	35	1-<5	40	1	23	3 m-<1	28
		2-<6	31			5-<10	40	3-7	49	5-<10	50	5-<10	55	2-5	26	1-<6	40
		6-18	55	5-14	35	10-<15	45	7-13	57	>10	55	10-<15	60	6-10, 11-17	31, 36	≥6	50
	DLP (mGy-cm)	0-<1	344	0-4	470	<1	420	0-3	578	3 m-<1	300	<1	480	0	260	<3 m	300
		1-<2	440			1-<5	540			1-<5	450	1-<5	660	1	350	3 m-<1	385
		2-<6	518			5-<10	660	3-7	843	5-<10	650	5-<10	850	2-5	420	1-<6	505
		6-18	910	5-14	600	10-<15	780	7-13	888	>10	800	10-<15	1000	6-10, 11-17	500, 620	≥6	650

25

International Ped CT DRL Comparisons – Abdomen and Pelvis

Exam	Parameter	Age Groupings (y) and National Pediatric Diagnostic Reference Levels															
		ACR DIR		Australia		Belgium		Canada		Germany		Japan		Korea		EU	
		Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL	Age	DRL
Abdomen & pelvis with contrast	$CTDI_{vol}$ (mGy)	0-<1	2.4	0-4	7	<1	-	0-3	3.8			<1	5	0	3	<1 m	-
		1-<5	2.9			1-<5	3	3-7	4.9			1-<5	6	1	4	1 m-<4	3.5
		5-<10	4.6	5-14	10	5-<10	4	7-13	6.1	5-<10	5.0	5-<10	7.5	2-5	5	4-<10	5.4
		10-<15	7.9			10-<15	6			10-<15	7.0	10-<15	9	6-10	6	10-<14	7.3
		15-18	11											11-17	9	14-<18	13
	DLP (mGy-cm)	0-<1	60	0-4	170	<1	-	0-3	120			<1	110	0	70	<1 m	45
		1-<5	100			1-<5	100	3-7	185			1-<5	190	1	80	1 m-<4	120
		5-<10	170	5-14	390	5-<10	150	7-13	263	5-<10	185	5-<10	265	2-5	200	4-<10	150
		10-<15	358			10-<15	280			10-<15	310	10-<15	450	6-10	300	10-<14	210
		15-18	511											11-17	500	14-<18	480

26

Wrap Up

27

Potential Limitations

- DIR uses automated data collection process and is not a random nor necessarily representative sample of facilities, examination, or patients for all US CT practice; however, DIR demographics suggest broad participation from all types of facilities
- DRLs are not developed for clinical indication…only examination type (clinical indication not provided to DIR via the RDSR/DICOM header)
- Exam code mapping is manual process so if exam is not tagged correctly may cause problems by skewing data
- Use of dose reduction techniques, such as iterative reconstruction, CT scanner type and detector configuration is not collected in the DIR

28

What's Next?

- Update the 2016 adult CT study to see what has changed (and to learn from our mistakes)
- The ACR DIR is evolving to include other examinations and once the methodology is mature, DRLs can be developed for them
  - ✓Fluoroscopy
  - ✓Digital radiography
  - ✓Nuclear medicine

29

In Summary

- ICRP 135 guidance used to develop US DRLs for the 10 most common adult and pediatric CT exams
- ACR DIR allowed for the collection of over 1.3 million adult exams from over 500 facilities and 1.5 million pediatric exams from over 1600 facilities of varying practice types across the entire US
- The DRLs will enable facilities to compare their dose indices against national benchmarks and optimize their protocols as necessary

ACR® AMERICAN COLLEGE OF RADIOLOGY
100th 1923 2023
A CENTURY OF QUALITY, INTEGRITY, LEADERSHIP & INNOVATION

30